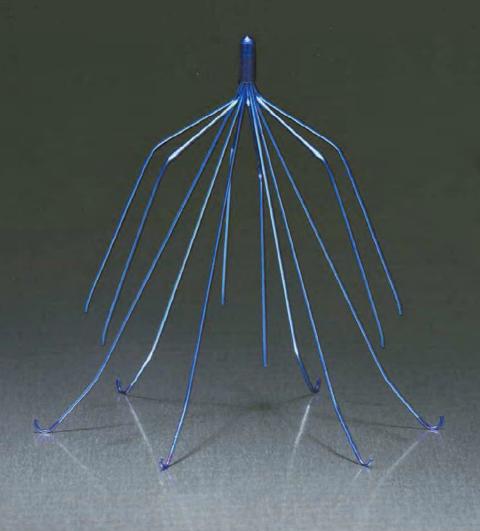
EXHIBIT Z (Filed Under Seal)

EXHIBIT AA

• G2 FILTER SYSTEM for Permanent Placement





INTRODUCING THE



for Permanent Placement

The G2™ Filter combines the **best design features** of Bard's existing vena cava filters to create a **brand-new permanent filter platform** — taking strength and stability to a new level.

- Increased MIGRATION RESISTANCE*
- · IMPROVED CENTERING*
- Enhanced FRACTURE RESISTANCE*

The newly enhanced G2™ Filter continues the Bard tradition of filter
INNOVATION spanning over a decade.

* Data on File

FINELESS PE

CLOT TRAPPING & CAVAL PATENCY

G2™ Filter utilizes the proven conical filter shape arranged into two offset layers that effectively trap large and small emboli without compromising caval patency.

SECURE FIXATION

Now featuring a wider leg span and thicker fixation hooks, the newly enhanced G2™ Filter resists migration across an even broader range of caval distension and higher pressures.*

* Maximum indicated caval diameter is 28 mm Data on File

LOW-PROFILE

7F delivery system is the lowest profile of any conical filter on the market.



SELF-CENTERING

Specially designed pusher wire and articulated arms promote a centered filter placement, even through tortuous anatomy.

AEORNANCE



ORDER INFORMATION

Catalog No.

Description

RF-310F

G2™ Filter System — Femoral Delivery Kit

DUVELCIAN'S PLONATION

For more information, contact:

Bard Peripheral Vascular, Inc. P. O. Box 1740 Tempe, AZ 85280-1740 USA

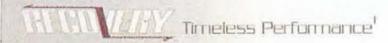
Tel: 1-480-894-9515 1-800-321-4254 Fax: 1-480-966-7062 1-800-440-5376 www.bardpv.com The safety and effectiveness of the G2 Filter System for use as a retrievable or temporary filter have not been established.

Please consult product tabels and package linearts for indications, contrainfications, hazards, warnings, cautions, and intermution for use. Rand and Treatest Performance are registered trademarks of C. R. Bad. Inc. or an affiliate. G2 is a trademark of C. R. Bad. Inc. or an affiliate. G2 is a trademark of C. R. Bad. Inc. or an affiliate. Section 1. Section 1.



EXHIBIT BB

RECOVERY Cone' Removal System



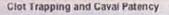


RECOVERY® Filter's unique selfcentering design, proven conical shape and bi-level filtering system create the ideal balance between clot trapping efficiency and caval patency. Advanced design and accurate placement coupled with lasting performance make RECOVERY® the permanent solution for caval

interruption.

Low Profile

 At 7F, RECOVERY® Filter's delivery system has one of the lowest profiles of any filter on the market.



 The RECOVERY® Filter utilizes the proven conical filter shape arranged into two offset layers to create a filtration system that effectively traps large and small emboli without compromising caval patency.

Self-Centering

 Articulated arms, along with the specially engineered flexible pusher wire of the delivery system, promote a centered placement.

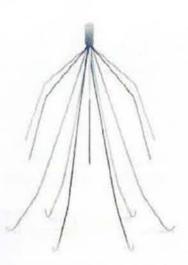
Latest Advance in Filter Technology

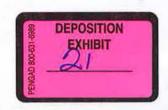
The RECOVERY® Filter, a product of Bard's Industry-leading nitinal experience, incorporates the best
features of today's most advanced caval fitration
devices while overcoming the disadvantages with
older designs.

Secure Fixation

 Fiter hooks are loaded into a delivery system that is specifically constructed to prevent leg crossing.

Bard, Recovery and Recovery Cone are registered trademarks of U. R. Bard, Inc., or an affiliate. Timeless Performance is a trademark of C. R. Bard, Inc., or an affiliate. Copyright 2004 C. R. Bard, Inc. At nights reserved. U.S. Patent: 6.007.658, 6.258.028. Legs Name.





Recovery Cone® Removal System for use with the Recovery® Filter and Foreign Body Retrievals



Instructions for Use

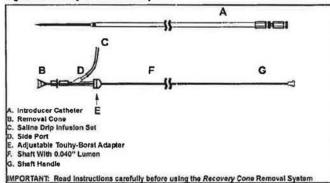
Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a

A. General Information
The Recovery Cone Removal System is intended to percutaneously remove the Recovery Filter or a foreign body as indicated.

The cone is designed to advance through its 75 cm, 10 French I.D. introducer catheter using a flexible, Pebax shaft. A reinforced cone at the end of the shaft is designed to collapse over the tip of the Recovery Filter or a foreign body for percutaneous removal. This cone is reinforced by a wire basket. The Introducer sheath has a radiopaque marker for enhanced visualization. The introducer sheath is used to collapse the removal cone over the Recovery Filter tip or a foreign body and pull the collapsed cone into the sheath to remove the Filter or foreign body.

B. Device Description
The Recovery Cone Removal System consists of the Recovery Cone and Introducer
Catheter (Figure A). The cone consists of a reinforced urethane cone, 15-mm in
diameter. The cone is connected to a plastic (Pebax) shaft and handle. The shaft has a
central lumen that accommodates a 0.035" guidewire. A Touty-Borst Y-adapter is used to
connect the cone to the Introducer Catheter and to a saline flush or drip. The Introducer
Catheter consists of a 10 French i.D. introducer sheath and dilator. The introducer sheath has a radiopaque marker for enhanced fluoroscopic visualization.

Figure A. Recovery Cone Removal System



C. Indications for Use

The Recovery Cone Removal System is intended for use to percutaneously remove the Recovery Filter or facilitate the retrieval of foreign objects from the peripheral vascular

D. Contraindications for Use None known.

- Do not attempt to remove the Recovery Filter If significant amounts of thrombus are trapped within the Filter or if the Filter tip is embedded within the vena caval wall
- Do not use excessive force when manipulating the cone. Excessive force may damage the catheter or other parts of the Recovery Cone.
- When attempting to retrieve a Recovery Filter, only use the Recovery Cone Removal System. Use of other devices has resulted in recurrent pulmonary embolism. Ensure adequate clearance in small vessels before deploying the Recovery Cone.
- Withdrawal of large foreign bodies may require a cut-down at the peripheral site.
- If resistance is experienced during the retrieval procedure, check the captured Filter or foreign body and introducer sheath using fluoroscopy.

 Contents are supplied sterile. Do not use if sterile barrier is damaged. If damage is
- found, contact your Bard representative.
- Single Patient Use Only. Do not reuse, reprocess or resterilize.

Do not use the device or accessories after the expiration date.

- Anatomical variances may complicate insertion and deployment of the device. Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
- Spinal deformations: It is important to exercise care when contemplating removing the Recovery Filter or a foreign body from the inferior vena cava with the Recovery Cone Removal System in patients with significant kyphosocilotic spinal deformations because the vessel may follow the general course of such anatomic deformations. This may require advanced techniques to remove the Filter or foreign body. Atter use, the Recovery Cone Removal System and its accessories and insertions supplies may be a potential biohazard. Handle and dispose of in accordance with
- accepted medical practice and with applicable local, state and federal laws and regulations.

 The size and location of the foreign body may impact its ability to be successfully captured and retrieved.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the potential complications. Possible complications of Recovery Cone usage include, but are not limited to, the following:

- Embolization
- Damage to the artery or vein
- Vessel tear or disruption
- Device entrapment
- Hematoma at the access site

NOTE: It is possible that complications such as those described in the "Warnings, Precautions and Potential Complications" section of this IFU may affect the recoverability of the device or foreign body and result in the clinician's decision to have the device or foreign body remain permanently implanted.

H. Equipment Required

The following equipment is required for use:

- Recovery Cone Removal System that contains:

 One 75 cm, 10 French I.D. delivery sheath and dilator set

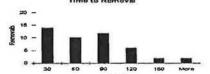
 One Y-adapter with Recovery Cone and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle 12 French dilator

- Sterile extension tube for saline drip or syringe for saline Infusion
 All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc

I. Clinical Experience with Recovery Filter
The Recovery Filter has been used in Canada by a single investigator and two colleagues at six Toronto area hospitals in 58 subjects, under the Special Access regulations.

Although essentially only one physician used the device, removal was performed by three physicians with different support staff and imaging equipment.

Of the 58 Filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 patients have died with Filters in place of causes unrelated to Filter placement or retrieval (leukemia, cancer, polyarteritis and pulmonary aspergillosis, and hemorrhagic stroke). Time to removal ranged from 1 to 161 days, average 60 days (see histogram).



Follow-up post retrieval has been an average of 325 days (range 1-901 days). Most (n=43) were retrieved via the right internal jugular vein, but some have been via the left internal jugular vein (n=1) and a collateral vein jugular (n=1). One was removed surgically during a cancer operation where the mess was impinging on the Filter. The two methods described in the Instructions for Use were used to retrieve the Filter in all but 4 cases, when a larger sheath was used, or a snare loop was attempted Instead of using the Recovery Cone System. There was one case of asymptomatic pulmonary embolism when using the larger sheath.

The only other adverse event reported was a fractured Filter arm and hook. This Filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the hook and the bony tissue of the hook into the h

Clinical Experience Summary Table		
Recovery Fitters Implanted	58	
Percutaneous Filter Removals	45	
Surgical Filter Removals	1 (Concurrent to tumor resection)	
Patient Age	8-89 years (52 years average)	
Reason for Filter Place	ement	
Contraindication to anticoagulation	40	
Complications associated with antilogulation	13	
Fallure of anticoagulation	3	
Prophylaxis	2	
Time to removal	1-161 days (60 days average)	
Follow-up post-removal	1-901 days (325 average)	
Filter Removal Compl	Ications	
Technical	0	
Hook fracture secondary to stresses due to labor and birth and infrarenal placement	1	
Asymptomatic pulmonary embolism post-removal	1	

J. Directions for Use - Recovery Filter Removal (See Section K for Foreign Body Retrieval Directions for Use)

Insertion of the Introducer Catheter

- Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis
- 2. Prep, drape and anesthetize the skin puncture site in standard fashion.
- Select and open the Recovery Cone® Removal System package. Open Kit A Introducer Catheter package
- Nick the skin with a #11 blade and perform venipuncture with an 18 gauge entry
- Insert the guidewire and gently advance it to the location of the Recovery® Filter for removal.
- Remove the venipuncture needle over the guidewire.
- Pre-dilate the accessed vessel with a 12 French dilator.
- 8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

- Remove the guidewire and dilator, leaving the Introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant
- saline drip infusion to maintain introducer catheter patency.

 10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the Filter. If there is significant thrombus within the Filter, do not remove the Recovery Filter.

Recovery Cone Insertion and Delivery

- Remove the cone and pusher system from Kit B.
 Flush the central lumen of the cone catheter and wet the cone with saline—preferably reparinized saline
- Slowly withdraw the cone into the Y-adapter to collapse the cone.

NOTE: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be easily delivered through the catheter. Device has been tested for the retrieval of foreign bodies in the femoral, jugular and subclavian venous systems.

- Connect a 500 mL bag or a syringe of saline to the sideport of the Y-adapter. Allow the saline infusion to flow around the removal cone in the Y-adapter for 5 seconds. Tighten the Touhy-Borst adapter valve to minimize reflux of saline toward the feeder, but not so tight as to prevent the pusher shaft from advancing freely
- 15. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and Filter delivery system should be held in a straight fine to minimize friction.
- Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
- Continue forward movement of the pusher wire until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheath to open the cone by stabilizing the shaft and retracting the catheter.

Capture of Recovery Filter Recovery Filter Removal

18. The capture of the Recovery Filter is illustrated in Recovery Filter Removal - Figures A-E:

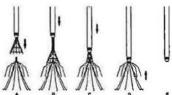


Figure A: After the cone has been opened superior to the Filter, advance the cone over the Filter by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the Filter tip

Figure B: Close the cone over the Filter tip by advancing the introducer catheter over the cone while holding the pusher shaft stationary

Figure C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.

Figure D: With the cone collapsed over the Filter, remove the Filter by stabilizing the Introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.

Figure E: The Filter has been retracted into the catheter.

Follow-up Venacavogram

- 19. A follow-up venacavogram may be performed after withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
- 20. Remove the introducer catheter and apply routine compression over the puncture site In the usual way to achieve hemostasis.

Guldewire - Assisted Technique

Due to anatomical variances with respect to the position of the Recovery Filter, guidewire assisted techniques may be used.

If it is difficult to advance the Recovery Cone System over the Recovery Filter tip, one

may use a guidewire to facilitate advancement of the cone.

Withdraw the introducer sheath and cone shaft away from the Filter tip. Insert a 0.035* guidewire through the central lumen (J-tipped or angled tip; a hydrophilic-coated guidewire is recommended). Advance the guidewire through the cone and through the Filter near the Filter lip.

After it has been confirmed that the guidewire is in contact with or in close proximity to the Filter tip, advance the cone over the guidewire to the Filter tip.

Advance the introducer sheath to slightly collapse the cone over the Filter tip. Withdraw the guidewire into the pusher shaft.

Continue removing the Filler as described in step 18.

K. Directions for Use - Foreign Body Retrieval

- Select a suitable entry site to access the foreign body.

 Prep, drape and anesthetize the skin puncture site in standard fashion.
- Select and open the Recovery Cone Removal System package. Open Kit A Introducer Catheter package
- Nick the skin with a #11 blade and perform puncture with an 18 gauge entry needle.
- Insert the guidewire and gently advance it to the location of the foreign body
- Remove the entry needle over the guidewire.

 Pre-dilate the insertion site with a 12F dilator and then advance the introducer catheter 7. together with its tapered dilator over the guidewire to the target area.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

- 8. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently with saline to maintain introducer catheter patency.
- Remove the cone and pusher system from Kit B.
- 10. Flush the central lumen of the cone catheter and wet the cone with saline-preferably heparinized saline.
- 11. Slowly withdraw the cone into the Y-adapter to collapse the cone

NOTE: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be easily delivered through the catheter. Device has been tested for the retrieval of foreign bodies in the femoral, jugular and subclavian venous systems.

- 12. Connect a 500 mL bag or a syringe of saline to the sideport of the Y-adapter. Allow the saline Infusion to flow around the removal cone in the Y-adapter for 5 seconds. Tighten the Toulty-Borst adapter valve to minimize reflux of saline toward the feeder, but not so tight as to prevent the pusher shaft from advancing freely.
- Attach the Y-adapter with the collapsed cone to the introducer catheler.
- 14. Advance the cone by moving the pusher shaft forward through the introducer catheter
- Continue forward movement of the pusher wire until the cone advances to the radiopaque marker on the distal end of the introducer catheter.
- Open the cone by stabilizing the shaft and retracting the catheter
 - After the cone has been opened adjacent to the foreign body, advance the cone over foreign body by holding the introducer catheter stationary and advancing the pusher
- Close the cone over the foreign body by advancing the introducer catheter over the
- cone while holding the pusher shaft stationary.

 Continue advancing the introducer catheter over the cone until the cone is within the Introducer catheter
- With the cone collapsed over the foreign body, remove the foreign body by stabilizing the introducer catheter and retracting the pusher shaft in one smooth, continuous

L. How Supplied

Each Recovery Cone Removal System is supplied preloaded. Each Recovery Cone Removal System is sterile and non-pyrogenic unless package has been opened or damaged, and is ready to be used for single use only. The Recovery Cone System is pre-assembled. Do not attempt to re-sterilize this product.

This product should be stored in a cool (room temperature), dry place.

Bard Peripheral Vescular warrants to the first purchaser of this product, that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion, or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your country

An issue or revision date and revision number for these instructions are included for the user's information on the last page of this booklet.

In the event 36 months have elapsed between this dato and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.



Recovery Cone® Removal System



Do Not Re-sterilize.

Recovery Cone® Removal System Introducer Catheter



Do Not Use If Package Is Damaged Or Opened.

REF

Catalog Number



Recommended Guidewire



Use By



Manufactured By



Lot Number



Contents: REF: FBRC Kit A: One (1) 10 Fr. Introducer Catheter 75cm Long with Dilator Kit B: One (1) Recovery Cone Removal System



Attention, See Instructions for Use



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Sterilized By Using Ethylene Oxide



U.S. Patent No. 6,156,055. Other Patents Pending. Copyright © 2007 C. R. Bard, Inc. All rights reserved. Printed In the U.S.A.

NON PYROGENIC

Non-pyrogenic



Single Use. Do Not Rouse.



Manufactured By: Bard Peripheral Vascular, Inc. 1625 West 3rd Street Tempe, AZ 85281 USA

TEL: 1-480-894-9515 1-800-321-4254 FAX: 1-480-966-7062 1-800-440-5376 www.bardpv.com

PK5014899 Rev. 0 11/07

EXHIBIT CC



Timeless Performance[†]

NOW AVAILABLE - JUGULAR DELIVERY SYSTEM



The Recovery[†] G2 Filter combines the best design features of Bard's existing vena cava filters to create a brand-new filter platform—taking strength and stability to a new level.

The newly enhanced Recovery[†] G2 Filter continues the Bard tradition of filter innovation spanning over a decade.

- Increased MIGRATION RESISTANCE*
- . IMPROVED CENTERING
- Enhanced FRACTURE RESISTANCE*
 Data on File

Clot Trapping and Caval Patency

The Recovery^T G2 Filter utilizes the proven conical lister shape arranged into two offset layers that effectively trap large and small emboli without compromising caval patency.

Secure Fixation

Now featuring a wider leg span and thicker fixation hooks, the newly enhanced Recovery^T G2 Filter resists migration across an even broader range of caval distension and higher pressures.*

* Maximum indicated caval diameter is 25 mm. Data on File



Low-Profile

7F delivery system is the lowest profile of any conical filter on the market.

Self-Centering

Specially designed pusher wire and articulated arms promote a centered filter placement, even through tortuous anatomy.

† Bard, Recovery and Timeless Performance are registered trademarks or trademarks of C, R, Bard, Inc. or an affiliate. Copyright 2005 C, R, Bard, Inc. All rights reserved. Legal Natice

Please consult product labels and package inserts for indications, contraindications, hazards, warnings, calabons, and information for use.

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Recovery Cone® Removal System for use with the Recovery® Filter and Foreign Body Retrievals



Instructions for Use

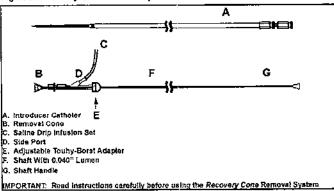
Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a

A. General Information
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B. Device Description
The Recovery Cone Removal System consists of the Recovery Cone and Introducer
Catheter (Figure A). The cone consists of a reinforced urethane cone, 15-mm in
diameter. The cone is connected to a plastic (Pebax) shaft and handle. The shaft has a
central lumen that accommodates a 0.035" guidewire. A Touty-Borst Y-adapter is used to
connect the cone to the Introducer Catheter and to a saline flush or drip. The Introducer
Catheter consists of a 10 French I.D. introducer sheath and dilator. The introducer sheath has a radiopaque marker for enhanced fluoroscopic visualization.

Figure A. Recovery Cone Removal System



C. Indications for Use

The Recovery Cone Removal System is intended for use to percutaneously remove the Recovery Filter or facilitate the retrieval of foreign objects from the peripheral vascular

D. Contraindications for Use None known.

- Do not attempt to remove the Recovery Filter if significant amounts of thrombus are trapped within the Filter or if the Filter tip is embedded within the vena caval wall
- Do not use excessive force when manipulating the cone. Excessive force may damage the catheter or other parts of the Recovery Cone.
- When attempting to retrieve a Recovery Filter, only use the Recovery Cone Removal System. Use of other devices has resulted in recurrent pulmonary embolism. Ensure adequate clearance in small vessels before deploying the Recovery Cone.
- Withdrawal of large foreign bodies may require a cut-down at the peripheral sit
- If resistance is experienced during the retrieval procedure, check the captured Filter or
- foreign body and introducer sheath using fluoroscopy.

 Contents are supplied sterile. Do not use if sterile barrier is damaged. If damage is found, contact your Bard representative.
- Single Patient Use Only. Do not reuse, reprocess or resterilize.
- Do not use the device or accessories after the expiration date.

- Anatomical variances may complicate insertion and deployment of the device. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
- Spinal deformations: It is important to exercise care when contemplating removing the Recovery Filter or a foreign body from the inferior vena cava with the Recovery Cone Removal System in patients with significant kyphoscoliotic spinal deformations because the vessel may follow the general course of such anatomic deformations. This may require advanced techniques to remove the Filter or foreign body.

 After use, the Recovery Cone Removal System and its accessories and insertions
- supplies may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and with applicable local, state and federal laws and regulations.

 The size and location of the foreign body may impact its ability to be successfully captured and retrieved.

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the potential complications.

Possible complications of Recovery Cone usage include, but are not limited to, the

- Pulmonary Embolism
- Embolization
- Damage to the artery or vein
- Vessel tear or disruption
- Device entrapment
- Hematoma at the access site

NOTE: It is possible that compileations such as those described in the "Warnings, Precautions and Potential Complications" section of this IFU may affect the recoverability of the device or foreign body and result in the clinician's decision to have the device or foreign body remain permanently implanted.

H. Equipment Required

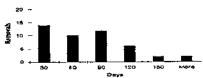
- The following equipment is required for use:

 Recovery Cone Removal System that contains:
 - One 75 cm, 10 French I.D. delivery sheath and dilator set
 - One Y-adapter with Recovery Cone and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- 12 French dilator
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

Clinical Experience with Recovery Filter

The Recovery Filter has been used in Canada by a single investigator and two colleagues at six Toronto area hospitals in 58 subjects, under the Special Access regulations Although essentially only one physician used the device, removal was performed by three physicians with different support staff and imaging equipment.

Of the 58 Filters implented, a total of 46 have been retrieved, 8 remain in place, and 4 patients have died with Filters in place of causes unrelated to Filter placement or retrieval (leukemia, cancer, polyarteritis and outmonary aspergillosis, and hemorrhagic stroke). Time to removal ranged from 1 to 161 days, average 60 days (see histogram).



Follow-up post refrieval has been an average of 325 days (range 1-901 days). Most (n=43) were retrieved via the right internal jugular vein, but some have been via the left internal jugular vein (n=1). One was removed surgically during a cancer operation where the mass was impinging on the Filter. The two methods described in the Instructions for Use were used to retrieve the Filter in all but 4 cases, when a larger sheath was used, or a snare loop was attempted instead of using the Recovery Cone System. There was one case of asymptomatic pulmonary embolism when using the larger sheath.

The only other adverse event reported was a fractured Filter arm and hook. This Filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of

Clinical Experience Summary Table		
Recovery Filters Implanted	58	
Percutaneous Filter Removals	45	
Surgical Fifter Removals	1 (Concurrent to tumor resection)	
Patient Age	8-89 years (52 years average)	
Reason for Filter Plan	cement	
Contraindication to anticoagulation	40	
Complications associated with anticoagulation	13	
Failure of anticoagulation	3	
Prophylaxis	2	
Time to removal	1-161 days (60 days average)	
Follow-up post-removal	1-901 days (325 average)	
Fitter Removal Compl	ications	
Technical	0	
Hook fracture secondary to stresses due to labor and birth and infrarenal placement	1	
Asymptomatic pulmonary embolism post-removal	1	

J. Directions for Use – Recovery Filter Removal

(See Section K for Foreign Body Retrieval Directions for Use)

Insertion of the Introducer Catheter

- Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference or location of venous
- Prep, drape and anesthelize the skin puncture site in standard fashion.
- Select and open the Recovery Cone® Removal System package. Open Kit A Introducer Catheter package
- Nick the skin with a #11 blade and perform venipuncture with an 18 gauge entry needle.
- Insert the guidewire and gently advance it to the location of the Recovery® Filter for removal.
- Remove the venipuncture needle over the guidewire.
- Pre-dilate the accessed vessel with a 12 French dilator.
- Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

- Remove the guidewire and ditator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency
- Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the Filter. If there is significant thrombus within the Filter, do not remove the Recovery Filter.

Recovery Cone Insertion and Delivery

- Remove the cone and pusher system from Kit B.
- Flush the central lumen of the cone catheter and wet the cone with saline-preferably hepannized saline
- 13. Slowly withdraw the cone into the Y-adapter to collapse the cone

NOTE: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be easily delivered through the catheter. Device has been tested for the retrieval of foreign bodies in the femoral, jugular and subclavian venous systems.

- 14. Connect a 500 mL bag or a syringe of saline to the sideport of the Y-adapter. Allow the saline infusion to flow around the removal cone in the Y-adapter for 5 seconds. Tighten the Toutry-Borst adapter valve to minimize reflux of saline toward the feeder, but not so tight as to prevent the pusher shaft from advancing freely.
- 15. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and Filter delivery system should be held in a straight line to minimize friction.
- Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
- Continue forward movement of the pusher wire until the cone advances to the radiopaque marker on the distall end of the introducer catheter. Unsheath to open the

cone by stabilizing the shaft and retracting the catheter.

Capture of Recovery Filter Recovery Fitter Removal

18. The capture of the Recovery Filter is illustrated in Recovery Filter Removal - Figures

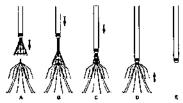


Figure A: After the cone has been opened superior to the Filter, advance the cone over the Filter by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is

Figure B. Close the cone over the Filter tip by advancing the introducer catheter over the cone while holding the pusher shaft stationary.

Figure C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.

Figure D: With the cone collapsed over the Filter, remove the Filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.

Figure E: The Filter has been retracted into the catheter

Follow-up Venacavogram

- 19. A follow-up venacavogram may be performed after withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
- 29. Remove the introducer catheler and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guldewire - Assisted Technique

Due to anatomical variances with respect to the position of the Recovery Filter, guidewire assisted techniques may be used.

If it is difficult to advance the Recovery Cone System over the Recovery Filter tip, one

may use a guidewire to facilitate advancement of the cone.

Withdraw the introducer sheath and cone shaft away from the Filter tip. Insert a 0.035 quidewire through the central turner (3-lipped or angled tip; a hydrophilic-coated quidewire is recommended). Advance the guidewire through the cone and through the Filter near the Fifter tip.

After it has been confirmed that the guidewire is in contact with or in close proximity to the Filter tip, advance the cone over the guidewire to the Filter tip.

Advance the introducer sheath to slightly collapse the cone over the Filter tip. Withdraw the guidewire into the pusher shaft.

Continue removing the Filter as described in slep 18.

- K. Directions for Use Foreign Body Retrieval
 Select a suitable entry site to access the foreign body.
- Prep, drape and anesthetize the skin puncture site in standard fashion.
- Select and open the Recovery Cone Removal System package. Open Kit A
- Introducer Catheter package.

 Nick the skin with a #11 blade and perform puncture with an 18 gauge entry needle.
- Insert the guidewire and gently advance it to the location of the foreign body.
- Remove the entry needle over the guidewire.
- Pre-dilate the insertion site with a 12F dilator and then advance the introducer catheter together with its tapered dilator over the guidewire to the target area.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

- Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently with saline to maintain introducer catheter
- Remove the cone and pusher system from Kit B.
- 10. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline
- 11. Slowly withdraw the cone into the Y-adapter to collapse the cone

NOTE: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be easily delivered through the catheter. Device has been tested for the retrieval of foreign bodies in the femoral, jugular and subclavian venous systems.

- Connect a 500 mL bag or a syringe of saline to the sideport of the Y-adapter. Allow the saline infusion to flow around the removal cone in the Y-adapter for 5 seconds Tighten the Touhy-Borst adapter valve to minimize reflux of saline toward the feeder, but not so tight as to prevent the pusher shaft from advancing freely.
- Attach the Y-adapter with the collapsed cone to the introducer catheler
- 14. Advance the cone by moving the pusher shaft forward through the introducer catheter.
- Continue forward movement of the pusher wire until the cone advances to the radiopaque marker on the distal and of the introducer catheter
- Open the cone by stabilizing the shaft and retracting the catheter After the cone has been opened adjacent to the foreign body, advance the cone over foreign body by holding the introducer catheter stationary and advancing the pusher shaft.
- Close the cone over the foreign body by advancing the introducer catheter over the cone white holding the pusher shaft stationary.
- Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.
- With the cone collapsed over the foreign body, remove the foreign body by stabilizing the introducer catheter and retracting the pusher shaft in one smooth, continuous motion

L. How Supplied

Each Recovery Cone Removal System is supplied preloaded. Each Recovery Cone Removal System is sterile and non-pyrogenic unless package has been opened or damaged, and is ready to be used for single use only. The Recovery Cone System is pre-assembled. Do not attempt to re-sterilize this product.

This product should be stored in a cool (room temperature), dry place.

M. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product, that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited, to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion, or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the taws of

An issue or revision date and revision number for these instructions are included for the user's information on the last page of this booklet.

In the event 36 months have elepsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.



Recovery Cone® Removal System



Do Not Re-sterlilze.

Recovery Cone® Removal System Introducer Catheter



Do Not Use If Package Is Damaged Or Opened.

REF

Catalog Number



Recommended Guldewire



Use By



Manufactured By



Lot Number



Contents: REF: FBRC Kit A: One {1} 10 Fr. Introducer Catheter 75cm Long with Dilator Kit B: One (1) Recovery Cone Removal System



Attention, See Instructions for Use



Bard, Recovery and Recovery Cone are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.



Sterilized By Using Ethylene Oxide



U.S. Patent No. 6,156,055. Other Patents Pending. Copyright © 2007 C. R. Bard, inc. All rights reserved. Printed in the U.S.A.



Non-pyrogenic



Single Use. Do Not Reuse.

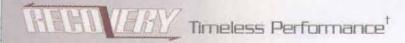


Manufactured By: Bard Peripheral Vascular, Inc. 1625 West 3rd Street Tempe. AZ 85281 USA

TEL: 1-480-894-9515 1-800-321-4254 FAX: 1-480-966-7062 1-800-440-5376 www.bardpv.com

PK5014899 Rev. 0 11/07

RECOVERY Cone® Removal System





RECOVERY® Filter's unique selfcentering design, proven conical shape and bi-level filtering system create the ideal balance between clot trapping efficiency and caval patency. Advanced design and accurate placement coupled with lasting performance make RECOVERY® the permanent solution for caval

interruption.

Low Profile

At 7F, RECOVERY® Filter's delivery system has one
of the lowest profiles of any filter on the market.

Clot Trapping and Caval Patency

 The RECOVERY® Filter utilizes the proven conical litter shape arranged into two offset layers to create a literation system that effectively traps large and small emboli without compromising caval patency.

Self-Centering

 Articulated arms, along with the specially engineered flexible pusher wire of the delivery system, promote a centered placement.

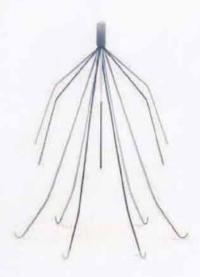
Latest Advance in Filter Technology

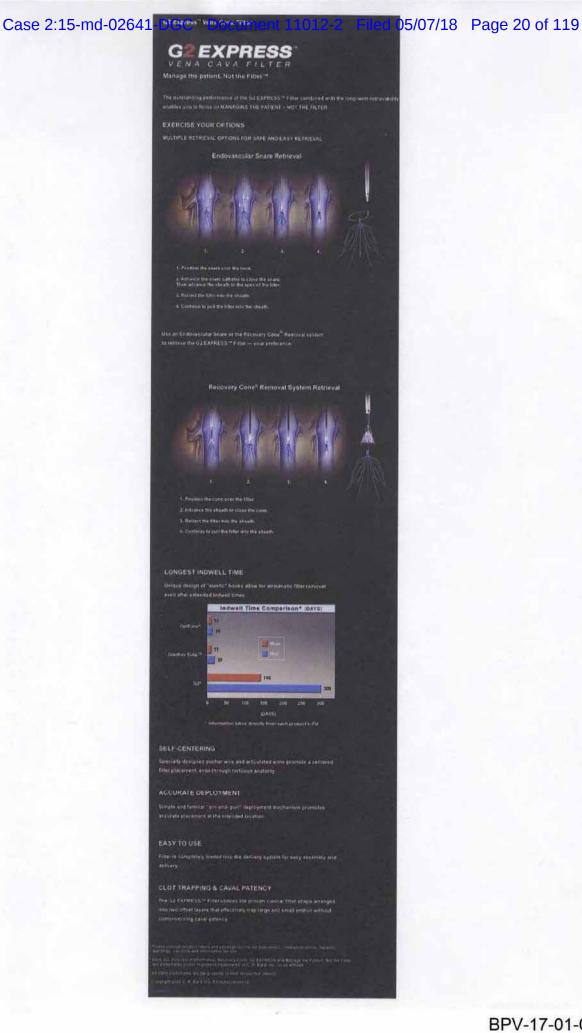
The RECOVERY® Filter, a product of Bard's industry-leading nitinol experience, incorporates the best features of today's most advanced caval filtration devices while overcoming the disadvantages with older designs.

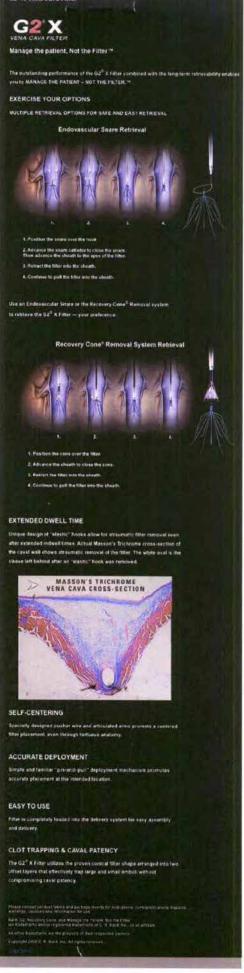
Secure Fixation

 Filter hooks are loaded into a delivery system that is specifically constructed to prevent leg crossing.

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HOW WILL THE FILTER BE INSERTED?

mined shape and is held in place against the year alled a catheter once inserted, the filter expands to opposite page. To make the procedure as sasy assible the fitter is inserted inside a small plastic t four physician will insert the filter through either the lett ternaral or jugolar vein (see anatomical illust

HOW LONG DOES THE PROCEDURE

and the specific encumistances, the implantation of filter generally takes loss than an hour USUALLY TAKE?

WILL I EXPERIENCE DISCOMFORT

DURING AND AFTER THE PROCEDURE? seture the procedure, will normally result in little to ocal anesthesia, blue a mild secative that might be to discomfort while the lifter is being implented

HOW LONG WILL IT TAKE TO FULLY RECOVER?

the specific length of lirse will very from patient to palie depending upon factors such as age, general state Recovery train the procedure should be rapid, airtig

The anatomical - this itentified below will provide peneral mider et nith se and that are engotian to unplan



THE IMPLANT PROCEDURE



annot take acticoagulants. Ecrithèse intividuals, a ven The most common treatment is a group of medication tre some patients who, for a variety of medical mass



back to the heart and longs - and remains in place to tr arge vein that carries blood from the lower extre lots belote they move further up toward the lungs signed to trap blood clots before they reach the

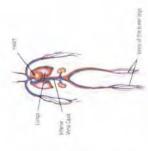


G2" X VENA CAVA FILTER

WHAT TYPES OF TREATMENT ARE USED

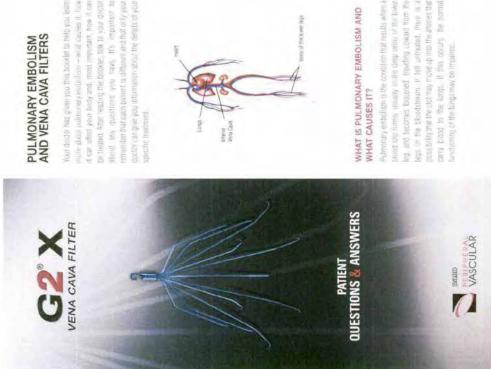
avaither may offer an effective treatment solution

WHAT IS A VENA CAVA FILTER?



WHAT IS PULMONARY EMBOLISM AND WHAT CAUSES IT?

sizes billiny that the clot may move up into the attenes that serry blood to the langs. If this occurs, the normal ing, and becomes loosened fraveling upward from to age in the bloodstream it left uniteated, there otening of the fungs may be impaired





AFTER THE PROCEDURE

HOW LONG WILL THE FILTER LAST?

the G2* A Fifty is designed to be a permanent implan mo with not need to be restitived, report transact, or replacer

CAN THE FILTER BECOME CLOGGED?

in the great majority of cases. The answer is "in" Once. our though the uppa cavazand the little will usuall descrive with apped in the other, the normal Year historial a rapped duti as the blood flows over 1.

IF I SHOULD NEED AN MRI EXAM, WILL THE METAL FILTER INTERFERE WITH THE TEST?

The COY X Filler is made them an alloy of motell and GENERAL AND WITH THE THE REPORT THE THE

SHOULD I CONTACT THE DOCTOR JNDER WHAT CIRCUMSTANCES RIGHT AWAY?

should contact your physician ount away II you special my or the following

- sudden onset of cheet pain recompanied for

CAN THE FILTER BE REMOVED? mexpaned (air mile audities)

The litter can be removed with your playings. mines that you no langest need it

Bard Peripheral Vascular, Inc. 1625 W. 3rd Street Tempe, AZ 65281 USA

IS THERE A "CUTOFF DATE" BY WHICH THE FILTER MUST BE REMOVED? WHEN CAN THE FILTER BE REMOVED?

VASCULAR

Tet. 1,480,894,9515 1,800,321,4254 Fax: 1,410,966,7062 1,800,440,5176

to GZP X FIRBI does not have a livry firmt in sensor in then the geant at willish you, no kinger med it. This is up that he temporal. The offer can be removed at any little

Please consult product block and package heart for includions, assumptioning Austria, worning, suddons and internation for san Bad GG and Trineisa Petermance are registered incluments of C. R. Bad. For, or an affiliate.

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RESUMING YOUR NORMAL LIFESTYLE

SHOULD I RESTRICT MY ACTIVITIES AFTER THE FILTER IMPLANTATION OR REMOVAL PROCEDURE?

he implantation or removal of a vena caya filter is not redical reasons for duing so. Be sure to distust with min director what level of activity is most appropriate for recessarily a reason to restrict your normal activity lovel however, sech palent is unique and there may be other

HOW WILL THE FILTER BE REMOVED?

You proper as will remove the filter through either the afters. Triguid' the catelet a drasping device will be charged to the life. The filler will be greased and the ulifor into the catheter. Your poys can will toon remov in page 4), Nesten will meet a small meetabled ight or effindemal jugular vein (see anatom - Hustran

HOW LONG DOES THE RETRIEVAL PROCEDURE TAKE?

Although It varies depending upon the Individual patter etherally takes took than are how

DURING AND AFTER THE PROCEDURE? WILL I EXPERIENCE DISCOMFORT

your mark for a lew days. This is noticed and wi SUPERIT YOU WIT DE THIT WITH EITHER THIS OF YOUR TID moved, Attenwants, you may expenience mild sonore As with the implant procedure, local arrestites in letped Built in Title to his dispersion with the "little to be motic sedative givon before the procedure, will not

HOW LONG WILL IT TAKE TO FULLY RECOVER FROM THE REMOVAL PROCEDURE?

BEOWER from the sensial presidence around the latest date of leagth old. Typically you will be thecharapatient, depending upon tadors such as age, genes Though the specific larger of this will say here pai everal (0-3) hours after the procedure

DOES THE FILTER HAVE TO BE REMOVED?

E. Telistic Strate deligned to be a permanent implant

REMOVAL PROCEDURE

BPV-17-01-00137598 LMD1



Jugular/Subclavian Vein Approach Instructions for Use



ENGLISH

Instructions for Use

For use in the Vena Cava

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a

A. General Information

The GZ* X Fitter is a venous interruption device designed to prevent pulmonary embolism. The unique design and material of the GZ* X Fitter provide filtering efficiency and allow percutaneous placement through an engiographic infroductor with minimum entry site difficulties. The prece-ment procedure is quick and simple to perform.

The $G2^{\bullet}$ X Filter is intended to be used in the inferior vena cave (IVC) with a diameter less than

or equal to 28 mm.
The jugular/subclavian system atows for placement of the GZ* X Fitter via a jugular or subclavian vern approach. The jugular/subclavian system consists of a dilator and introducer set and a devery device. The dilator accepts a 0.036* guidewire and allows for an 800 psi maximum pressure contrast power injection. The 15 Fench Lip introducer sheath contrast a radiopaque tip and hampostasis valve with a side port. The delivery device fits within the introducer sheath and consists of a side port for saline influsion and a dalivery machanism to deploy the GZ* X Filler. The delivery device contains a spine cap that nechanically separates, the filler anchors from one another in a unique pattern to prevent leg entanglament. The GZ* X Filler. Filler beloaded within the delivery device. Once the kitroducer sheath is within position, the delivery cevice is advanced through the introducer sheath in the introducer and delivery tubbs snap together. The safety city at their removed. The introducer hub is pulled back over the puebler wise thandle to ussheaths and release the GZ* X Filter allowing it to recover to its precelemnined shape.

The G2* X Sittle is designed to act as a permanent lister. When childsity indicated, the G2* X Filter may be percutenaously removed after Implantation according to the instructions provided under the Optional Removal Procedure. The G2* X Filter's anchors allow the filter to remain rigid and rosts infigration, but classically deform when the filter is precludaneously removed (reference Optional Procedure for Filter Removal for specific removal instructions).

MRI Sefety:

MRI Sefory:
The GT X Filler was determined to be MR-conditional according to the remninology specified in the American Society for Testing and Naterials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Salety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

Constructions, remayerants, curis.

Nor-clinical learning demonstrated that the GZ* X Fitter is MR Conditional. A patient with this implant can be scanned safety immediately after placement under the following conditions:

-Static magnetic field of 3 Fasts or loss:

-Spatial gradient magnetic field of 728-Gaussiam or less:

-Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3-Wikg for 15 minutes of scanning.

In non-clinical testing, the G2° X Filter produced a temperature rise of 0.8°C at a maximum MR system-reported which body everaged specific absorption rate (DAR) of 3-Wing for 15-minutes of MR cyanning in a 3-Testa MR system using a transmit/raceive body coll (Excila, Software G3.6-0528, General Elector, Healthcare, Mixaukes, WI).

NR image quality may be compromised if the area of interest is in the exact same area reliablely close to the position of the GZ*X Filter. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

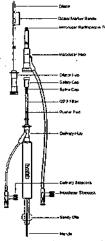
B. Device Description

b. Userica Description The GZ* X Filter System - Jugular/Subclavian consists of the filter and delivery eyetem. The GZ* X Filter can be delivered via the femoral and jugular/subclavian approaches. A separate delivery system is available for each approach.

The GJT X Filter consists of twelve shape-memory clinol wires emanating from a central ncinol sleeve with a ravieval hook at the apax of the filter. These twelve wires form two levels of Bitation of embodi: the legs provide the lower level of filtration and the arms provide the upper level. of fitration

The GZ* X Filter System - Jugular/Subclavian is Illustrated in Figure 1. The Dalivery System consists of a 16 French I.D. minducer sheath and distor, the GZ* X Filter, and a delivery device. The GZ* X Filter is packaged pre-loaded within the delivery device.

Figure 1: GT X Filter System - Jugular/Subclavian



IMPORTANT: Read Instructions carefully before using the GZ X Filter

C. indications for Use
The G2* X Filter - Jugular Subclavian is indicated for use in the prevention of recurrent pulmonary embolism via permanent processes in the following situations:

Output

Description:

- Pulmonary thromboemboism when anticoagulants are contraindicated. Failure of anticoagulant therapy for thromboembotic disease.
- Emergency treatment following massive pulmonary embolism where anticloated benefits of conventional therapy are reduced. Chronic, recurrent pulmonary embolism where articoagulant therapy has larted or is con-
- traindicated

 GZ* X Filter may be removed according to the instructions supplied under Section labeled:

 Optional Procedure for Filter Removal.

D. Contraindications for Use

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

The GZ* X Filter should not be implanted in:

- Pregnant patients when fluoroscopy may enganger the fatus. Risks and benefits should be assessed carefully
- Patients with an IVC diameter larger than 28 mm.
- Patients with risk of septic embolism

Case 2:15-md-02641-DGC Document 11012-2 Filed 05/07/18 Page 28 of 119

- The GZ X Filter is pre-loaded and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the GZ X Filter cannot be safely reload-
- 2. Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution
- 3. If large thrombus is present at the initial delivery alto, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an elternate elte to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.
- Never re-deploy a removed filter.
 Never advance the guidowire or introducer sheath/dilator or deploy the filter without fluoroscopic guidance.
- Filter fractures are a known complication of yens cava filters. There have been some
- 6. Filter fractures are a known complication of vers cava filters. There have been some reports of serious pulmonary and cardiac complications with vens cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
 7. Movement, migration or till of the filter are known complications of vens cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in V/Cs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or distorgement dure to large clot burdons.
 8. Naver use the juguitar or subclavian delivery system for famoral approach, as this will result in improper GZ*X Filter orientation within the IVC.
 9. When intesting contrast modium through the dilator, do not exceed the maximum pres-
- When injecting contrast modium through the dilator, do not exceed the maximum pres-aure rating of 800 psl.
- 10. Parsons with allergic reactions to nickel may suffer an allergic response to this
- 11. After use, the GZX Filter and accessories may be a potential biohazard. Handle and dispusse of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Reterance Potential Complications section for further information regarding other known

GZ* X Filter Removal

 Do not attempt to remove the G2° X Filter if eignificant amounts of thrombus are trapped within the filter or if the ratheval hook is embedded within the vena ceva wall. NOTE: It is possible that complications such as those described in the "Warnings,"
"Precautions," or "Potential Complications" sections of this instructions for Use ma affect the recoverability of the device and result in the clinician's decision to have it device remain permanently implanted.

- Nover re-deploy a removed filter.
 Remove the GZ X Filter using an intravascular snare or the Recovery Cone® Removal System only. Refer to the Optional Procedure for Filter Removal section for details.

F. Precautions GZ X Fitter implantation

- This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.
- 2. This device has neither been studied in pregnant women, nor in suprarenal placement pos-
- 3. Anetomical variances may complicate filter insertion and deployment. Careful attention to those instructions for Use can shorten insertion time and reduce the likelihood of difficulties.

 4. Position the retrieval hook 1 cm below the towest renal vein. Venecavography must always be parformed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
- cuestly show the was on the type, may be misleading. When measuring caval dimensions, consider an angiographic catheler or intravascular. What sound (tytus) if there is any question about coval morphology. If misplacement, sub-optimal placement, or litting of the fitter occurs, consider immediate ramoval. Do not attempt to reposition the filter, Retireve the GE* Kustrg an intravascular since or a Recovery Cons* Removal System only. Refer to the Optional Procedure for Filter Removal section for details.
- 7. Spinel deformations: It is important to exercise core when contemplating emphantalion in patients with significant hyphosocirotic spinel deformations because the IVC may follow the general course of such anatomic deformations. This may make perculaneous removal of the filter most deficult. er more difficult.
- In patients with continued risk of chronic, recurrent pulmonary ambolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
- 9. If resistance is anonunlared during the insertion procedure, withdraw the guidewire and check velto patency fluorescopically with a small kilection of contrast medium. If a large fluoribus is present, remove the venipuncture needle and use the vein on the opposite side. A small
- brombus mey be bypassed by the guidewire and introducer.

 10. Ensure that the introducer and the delivery device hubs are seapped logather and the system has been positioned for optimal placement, before deploying the GZ* X Filter.
- 11. Do not remove the safety clip until the introducer and the delivery device hubs are snapped
- 12. Do not deliver the filter by pushing on the handle, rather retract the introducer hub to properly ieploy the G2 X Fiter.
- 3. It is very important to maintain introducer patency with a saline flush to prevent occlusion of the introducer, which may intenfere with delivery device advancement.

 14. Applicating the introducer sheath while teaving the guidewire in place may tead to the introduction of air into the system.

G2 X Filter Removal

- Anatomical variances may complicate the removal procedure. Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
- instructions for Use can shorten insertion time and reduce the likelihood of difficulties. Spinal deformations: It is Important to exercise care when contemplating removing the Caff XF live with the Recovery Cone® Removal System in patients with significant kychoscolious spinal deformations because the IVC may follow the general course of such anatomic deformations. This may require advanced intervantional techniques to remove the filter. When using the Recovary Cone® Removal System, the cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

NOTE: Standards and guidelines developed by the Society of Interventional Radiolog recommend that patients with filters (either permanent or retrievable) be tracked and receive "routine follow-up" subsequent to the placement of the device.

receive "routine rollow-up" subsequent to the placement of the device.

See Reporting Standards for Inforior Vene Caval Fifter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Options Fifters. Millivero, S., et al.: J. Vesc Inter Radiol 2005; 16:441-443: Recommended Reporting Standards for Yons Cave Fifter Placement and Patient Follow-up. The Participants in the Yono Cavel Fifter Consensus: Conference: J Vasc Inter Radiol 2003; 14:S427-S432; Guidelines for the Use of Retrievable and Convertible Vena Cavel Fifters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. Kaufman, J., et al.: J Vasc Interv Radiol 2006; 17:449-459.

G. Potential Complications

Procedures requising perculaineous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or

Possible complications include, but are not limited to, the following:

- soble complications include, but are not limited to, the following:
 Movement, ingration or sit of the filter are known complications of vana cava filters.
 Migration of filters to the heart or lungs has been reported. These have also been reports of caudat migration of the filter, Migration may be caused by precedent in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots end/or dislodgement due to targe clot.
- Fifter fractures are a known complication of vane cava filters. There have been some reports of serious pulmonary and cardiac complications with vene cava filters requiring the raidleval of the fragment utilizing endovascular and/or surgical techniques.

Case 2:15-md-02641-DGC Document 11012-2 Filed 05/07/18 Page 29 of 119 • Perforation or other acute or chronic damage of the IVC wall.

- Acute or recurrent pulmonary embolism. This has been reported despite filter usegs, it is not known if thrombi passed through the filter, or originated from superior or collateral
- Dasp vain thrombosis
- Cavel thrombosis/occlusion.
- Extravasation of contrast material at time of venecavogram
- Air embollem
- Remetoma or nerve injury at the gunsture site or subsequent retrieval site.
- egarnomeH
- Restriction of blood flow
- Occusion of small vessels
- Distal embolization.
- Intime. teen
- Stenosis at implant site.
- Failure of filter expansion/ moomplete expansion
- Insertion site thrombosis
- Filter malposition
- Arteriovenous fistula
- Back of abdominal pain
- Filler Till
- Hemo:horax
- Phiagmasia cerulos dolens
- Pneumothorax
- Postphiebitic synérome
- Stroke
- Thrombook abilis
- Blood Loss
- Guidewire entrapment

All of the above complications may be associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vene cave alliver is morbidly obese patients. The riskibenefit ratio of any of these complications should be weighed against the inherent riskibenefit ratio for a patient who is at risk of pulmodary embolism without intervention.

H. Equipment Required

- One GZ X Filter Jugular/Subclevian System that contains:
 - •One 55 cm. 10 French I.D. Introduces and dilator set One delivery device with pre-fosded 92° X Filter
- 9.038* 3 mm J-tipped Guldawire, 110 cm tong or longer
- 18G entry needle
- Saline
- Contrast medium
- Sterile extension tube for ealine drip or syninge for saline infusion
- All basic materials for verigencture: scalpel, #11 blade, local anesthesia, drapes, etc.

I. Directions for itea

- Redict a surfable juggifar or subclavien venous access route, on either the right or left side. depending upon the patient's size/anatomy, operator's preference, or tocation of venous.
- Prep, drape, and anasihetize the skin puncture sile in standard lashion
- Select and open the carton and outer pouch. Open the introducer sheath and dilator inner
- Nick the skin with a #11 blade and perform ventpuncture with an 18G entry needle Insert a J-typed guidawire and gently advance 4 Into the inferior vena cava
- PRECAUTION: If resistance is encountered during the insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is present, remove the vention characteristic time vain on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

5. Remove the 18G entry medie over the J-typed guidewise. Obtain the citator and the introducer sheath from the package. Flush the difator and the introducer with salins. Insert the difator through the introducer sheath ensuring that the trubs anap logether. Advance the 10 French introducer sheeth together with its topered difator over the guidewire and into the infe-

NOTE: A 0.038° guidewire is used to guide the dilator/infroducer assembly beyond the implant site to ensure proper advancement.

PRECAUTION: It is very important to maintain introducer patency with a sailine flush to prevent occlusion of the introducer, which may interfere with delivery davice advance-

7. Remove the guidewire and perform a standard inferior venecevogram (typically 30 mt, of contrast medium at 15mL/s) through the dilator. Check for cavel thrombt, position of rend velne, and congenital anomalies. Select the optimum level for filter placement and measure the fVC diameter, correcting for magnification (typically 20 percent).

NOTE: IVC diameter may be measured using dilator radiopaque marker bande. Marker bands are spaced at a distance of 28mm (outer-to-outer), which references the maximum indicated IVC diameter (Reference Figure 2).



WARNING: When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 800 psi.

WARNING: If the vens cave diameter is greater than 28mm, do not doploy the GT^*X -filter. If large thrombus to present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.

8. Separate the dilator and introducer hubs by bending and then pulling apart (Reference Figure 3). Romove the guidewire and diletor, leaving the 10 French introducer sheath with its tip in the interfor vene cover. Flush intermittently by hand or other to the introducer stopcock a constant patine drip influeion to maintain introducer patiency.



Open the delivery system inner pouch. Remove the delivery device from the package and e the red satety cap (Reterence Figure 4).



- Flush the delivery device with saline (arough the delivery stopcock)
- Insert and advance the delivery device through the introducer sheath until the introducer and delivery device hubs anap together (Reference Figure 5).

PRECAUTION: Ensure that the introducer and the delivery device hubs are enapped together and that the system has been positioned for optimal placement, before deploying the GT X Filter.

NOTE: Do not remove the safety clip until step #13.



Under fluoroscopic control, position the system for optimal placement. The distallend of the pusher pad provides a radiopaque indicator for positioning purposes (Reference Figure 8).

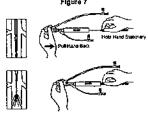
NGTE: Do not remove the safety clip until step #13.



NOTE: A gap between the filter apax and pusher pad is normal.

- 13. Remove the safety dip from the delivery device.
- 14. Stabilize the handle and pull back on the introducer hub (blue) to retract both the introducer shealth and delivery device. Retract the introducer hub until the handle bottoms out against the proximal edge of the delivery catheter hub (white). This will revease the GZ X Filter into position (Reference Figure 7).

PRECAUTION: Do not deliver the filter by pushing on the handle, rather retract the introducer hub to properly deploy the $GT \times Filter$.



- Separate the delivery and introducer hubs by bending and then pulling apart. Retract and remove the delivery device from the introducer sheath.
- Perform a venecevogram to confirm satisfactory deployment before terminating the procedure (typically 30mt, of contraet medium at 15mL/s).
- Remove the Introducer shaeth and apply routine compression over the puncture side in the
 usual manner to achieve homostasis

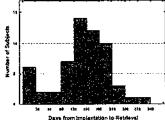
OPTIONAL PROCEDURE FOR FILTER REMOVAL:

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

Clinical Experience

A clarical study involving 160 patients was conducted to assess the safety of removal of the C2* X-Fitter. St patients underwert a filter retrievel procedure in which 58 had successful certieval of their filter. Of the 42 patients that did not have their filter retrieved, 6 dide of unrelated causes, 3 withdrew, 2 became lost to follow up and 31 were either not clinically indicated for filter retrieval or failed to meet retrieval eligibity or filter actively a per the protocol (within 6 monits after filter placement.) The mean age of the 61 patients who underwent a retrieval procedure was 48 years with a range of 19.3-81.6. The indications for filter placement included DVT and/or PE with contraindication to anticoagulation, DVT and/or PE with complication of failure of anticoagulation, and prophylaxis. The time to retrieval in the 58 patients with successful filter retrievals ranged from 5 to 300 days with a mean of 140 days and model or 144 days. Pleass see the histogram in Figure 8 depicting the mean of the filter of the filter active for the filter of the filter active filter active and the filter of the filter active filter active and prophylaxis. a mean of 140 days and median of 144 days. Please see the histogram in Figure 8 depicting the

Figure 8: Distribution of Filter Indwell Time in Retrieved Subjects



Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the litter apex with the Recovery Come* Removal System due to filter titl leading to embedding of the filter apex into the vana caval wall. One of the 58 successful filter retrieval involved a filter that was retrieved in spite of till and associated embedding of filter apex into

caval wall. There was one symptomatic complication in the study. A patient reported low back pain after a successful filter placement. On pre-ratifieval Imaging, two (2) of the filter arms were found to be penetrating the caval wall. The filter was successfully retrieved and the pain resolved. Asymptomatic complications included caudal migration (n=10, fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).

Removat of G2* X Filter Using an Intravescular Spare Equipment Regulated

- One intravascular snare of user's choice
- One 80-cm Introducer sheath 7F.ID or greater, to be used as retrieval sheath 0.035* 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry reedle Saine
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline Infusion.
 All basic materials for vanipuncture: scalpst, #11 blade, local anesthesia, drapes, etc.

- Prior to use, flush the retrieval sheath with heparinized saline or sultable Isotonic solution Prepare all other procedure components according to the manufacturers' Instructions for Use
- Use appropriate technique to determine that the filer, the jugular retrieval route, and distal IVC are free of thrombus.
- Select the appropriate loop diameter size of the intravescular snare
- Assemble the intravascular snare according to the instructions for Use provided by its manu-
- Insert the guidewire of chace into the reviewal sheath using the guidewire tip-straightener.
 Gently advance the guidewire into the tVC under fluoroscopic guidance such that it is caudal to the filter.
- nately 3cm cephalad to the fiber cetteval sheeth such that the tip of the sheath is approximately 3cm cephalad to the fiber cetteval book.
- Remove the guidawire.
 Insert and advance the intravescular share assembly through the sheath until it provides out
 of the sheath such that the marker band of the share catherer is dephaled to the filter retrieval.
- The representation of the GZ* X Firter using an intravascular share is illustrated Figure 9 A-E: Retrieval of GZ* X Fifter using an intravascular Share, litustrated

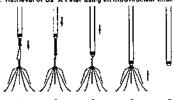


Figure 9 A: Slowly advance the loop forward over the litter apex.

Figure 9 B: Reduce the keep diameter by advancing the share cetheter white simultaneously pulling the share backwards until the pop engages the filter retrieval book.

NOTE: Ensure that the loop of the snare has properly engaged the retrieval hook and that the retrieval hook, retrieval catheter and share are aligned. Be careful to share the apox of the retrieval hook; not the side. The marker band of the share catheter must be caphalad to the retrieval hook.

NOTE: Always maintain tension on the snare to prevent disengagement of the snare loop from the filter retrieval hook.

Figure 9 C: Advance the sheath in the caudal direction until it aligns with the distal tip of the

Figure 9.D: White keeping tension of the snare, hold the retrieval sheath stationary and wilhdraw the filter into the retrieval sheath by retracting the intravascular snare.

Figure 9 E: Continue retracting the snare until the fitter is completely collapsed inside the sheeth. Once the fitter is fully collapsed inside the sheeth, retract the complete system as a unit out through the sheath.

WARRING: Do not attempt to remove the $G2^{\circ}$ X filter if eignificant amounts of thrombus are tropped within the fifter or if the retrieval hook is embedded within the vens caval wall.

WARNING: Remove the GT X Fifter using an intravescular snare or the Recovery Const Removal System only.

- 13. Examine the litter to assure that the complete filter has been removed
- Follow-up Venacavogram

 14. A follow-up venacavogram may be performed prior to withdrawing the infimition callbeild (typically 36 m), of contrast medium at 15 mL/s).
- Remove the introducer catheter and appty routine compression over the puncture site in the seual way to achieve hemostasis.

Removal of G2" X Filter Using the Recovery Cons® Removal System

Equipment Required

The following equipment is required for usa:

- Doe Recovery Cone® Removel System that contains:

 -One 75 cm, 19 French I.D. Introducer catheter and dileter set

 -One 75 cm, 19 French I.D. Introducer catheter and dileter set

 -One Y-adapter with Recovery Cone® Removel System and pusher delivery system

 0.035*3 mm J-hpped Guidewire, 110 cm long or longer
- 18 gauge entry needle 12 French dilator
- Saine
- Contrast medium Stanie extension lube for saline dup or syringe for saline intusion
- All basic materials for venipuncture; scalpel, #1" blade, local enesthesia, drapes, etc.

If the physician chooses to use the Recovery Cone* Removal System to remove the $G\mathcal{T}$ X Filter, it is available from C. R. Bard, Inc.

Procedural Instructions

Insertion of the introducer Catheter

- Select a suitable jugular venous access roule on either the right or left side depending upon the pattent's size or anatomy, operator's preference, or location of venous thromossis. Prep, drape and enesthetize the skin puncture size in standard fashion.
- Select and open the Recovery Cone® Removal System package. Open Kit A Introducer
- Nick the skin with a #11 blade and perform vanipuncture with an 18-gauge entry needle. Insert the guidewire and gently advance it to the location of the G2* X Filter for removal.
- Remove the venipuncture needle over the guidawite.
- Per-dilate the accessed vessel with a 12 French delator.

 Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein, such that the tip of the sheeth's approximately 3cm cephated to the filter. ₽.

NOTE: The introducer catheter has a radiopaque marker at the distal and of the cathates sheath to assist in visualization.

- Remove the guidewine and dilator, tearing the introducer cathotor with its tip in the appropriate focation. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
- 10. Perform a standard inferior venacavogram (typically 30 mt, of contrast medium at 15 mL/s). Chack for thrombus within the litter. If there is significant thrombus within the filter, do not remove the G2 X Filter.

Recovery Cone® Removal System Insertion and Dalivery

- 11. Remove the Recovery Cone* Removal System and pusher system from Kit B, 12. Flush the central lumen of the cone catheter and wat the cone with satine—preferably hepa-
- 13. Loosen the Toughy-Borst and slowly withdraw the cone into the Y-suspter to collapse the cone and fush with saline.

PRECAUTION: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly dalivered

14. Attach the male and of the Y-adapter with the collapsed cone disectly to the introducer catheter. The Introducer catheter and the retrieval cone system should be held in a straight. tine to minimize friction.

- retrieval of the GZ* X Filter using a Recovery Cone* Removal System is illustrated in

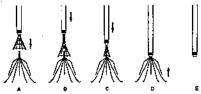


Figure 10 A.E: Retrieval of GZ* X Fifter using Recovery Cone* Removal System, Illustrated regule to Aria: recrease or set at hiner using recovery Cone* Removal System, Illustrated Figure 10 A: Atter the core has been opened superior to the filter, carefully advance the core over the retrieval hook by holding the introducer catheler stationary and advancing the pusher sheft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the retrieval hook.

Figure 10 B: Close the cone over the retrieval hook by advancing the introducer catheler over the cone while holding the pusher shaft stationary.

Figure 10 C: Continue advancing the introducer catheter over the cone until the cone is within the

Figure 10 E: The filter has been retracted into the catheter.

WARNING: Do not attempt to remove the GZ* X Filter if significant amounts of thrombus are trapped within the filter or if the retrieval book is embedded within the vens cava wall. WARNENG: Remove the GZ X Filter using an intravascular snaro or the Recovery Cone Removal System only.

NOTE: It is recommended to fluoroscopically image the filter in AP and lateral views during rotrieval.

NOTE: If difficulty is encountered while attempting to engage the ratrieval hook and/ or multiple passes are required, consider using an intravascular state as an alternate retrieval method.

18. Examine the fitter to assure that the complete fitter has been removed.

Fellow-up Venacavogram

- A follow-up venacovogram may be performed prior to whitebrawing the introducer catheter (typicality 30 mL of contrast medium at 15 mL/s).
- Remove the Introducer catheter and apply routine compression over the puncture site in the usual way to action themostasts.

Guidewire - Assisted Tachnique Due to enatomical variances with respect to the position of the $GZ^{\bullet}X$ fixer, guidewire-essisted techniques may be used.

Use of a Guidewim
If it is difficult to align the cone with the GZ* X retrieval hook, a guidewire could be used to lacilitate advancement of cone over the retrieval hook.

Withdraw the introducer cathetes and cone shaft away from the rettlevel hook. Insert a 0.035*
260cm guidewire through the centrel timen (a stiff guidewire with J or angled tip is recommended). Advance the guidewire through the cone and through the filter cear the cettlevel hook. ad). Available as governed that the goldewire is in contact with or in close proximity to the retrieval thook, solvence the cone over the goldewire to the retrieval hook.

Anyence the introducer catheler to stightly collapse the code over the retrieval hook. Withdraw the goldewire into the pusher shaft. Continue removing the filter os described in step 17.

J. How Supplied

J. How Supplied Each QZ^*X Filter is supplied preloaded in a delivary device. Each QZ^*X Filter is sterile and non-pyrogenic unless the package is damaged or opened, and is ready for single use only. If the Differ is inadvenently discharged, do not attempt to re-sterilize or reload it. WARNING: After use, the QZ^*X Filter and accessories may be a potential blohazard. Handle and dispose of in accordance with excepted medical practice and applicable local, state and federal laws and regulations.

The GZ" X Filter should be stored in a cool (room temperature), dark, dry place.

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be tear or respineral vascular warrants to the tirst purchaser of this product that this product will be tree from defects in materials and workmarship for a period of one year from the date of flat purchase and liability under this limited groduct wearanty will be limited to repair or replacement of the defective product, in Sard Peripheral Vascular's sole discretion or refunding your net price pold. Wear and teer from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

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Some states/countries do not allow an exclusion of implied warranties, incidental or conseq damages. You may be entitled to additional remedies under the laws of your state/country

An esue or revision date and a revision number for these instructions are included for the user's An essel of revision date and a terrotom further for water from the first product on the last page of this bookiet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vescular to see if additional product information is available.

For additional vena cava filter clinical information please refer to the following societal

- guidelines:
 "Practice Guideline for the Performance of Percutaneous Inferior Vene Cave Filter
 Placement for the Prevention of Pulmonary Embolism" (ACR Practice Guideline 2007;
- "American College of Chest Physicians: Opinions regarding the diagnosis and management of venous thrembogmbolic diagoos. ACCP Consensus Committee nanagament of venous thromboombelle disease. ACCP Consensus Committee on Julmonery Embosem. American College of Chest Physicians" [Chest 1998 Feb; 113(2):
- 499-504) "Practice Management **Practice Management Guidelinss for the Prevention of Venous Thromboembolism in Trauma Patients: The EAST Practice Management Guidelinss Work Group" [J Treuma
- "Quality Improvement Guidelines for Perculaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [JVIR 2003; 14:S271-S275]

- Cuality improvement Guidelines for Percutaneous Permanent Interior Vena Cava Filter Placement for the Prevention of Pulmonary Embotism, Grassi, Swan, Cardella, et al.: J Vasc Interv Radiol 2003; 14:S271-S275.

- Interv Radiol 2003; 14:S271-S275.

 Intial Experience In Humans with a New Retrievebte Inferior Vena Cava Filter, Asch, M.: Radiotogy 20102, 225(3), 805-844.

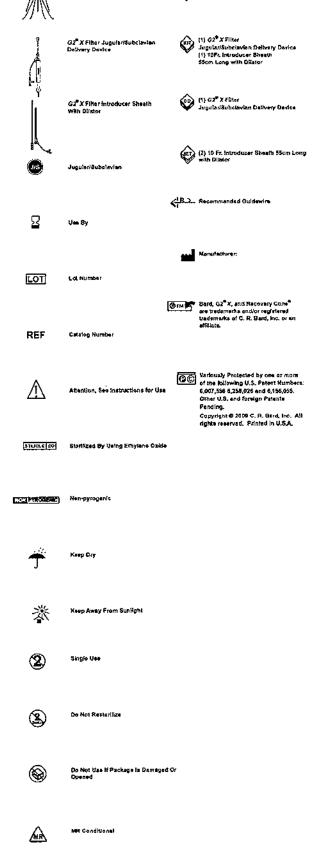
 Retrievability of the Recovery Vena Cava Filter After Dwall Times Longer than 180 Days, Binkert, C., et al.: J Vasc Interv Radiol 2006, 17(2), 299-302.

 Experience with the Recovery Filter as a Retrievable Inferior Vena Cava Filter, Grande, J., et al.: J Vasc Interv Radiol 2005, 16(9), 1189-1193.
- Difficult Retrieval of a Recovery IVC Filter, Hagsplet, K., et al.: J Vasc Interv Radiol 2004.
- Removal of Vena Cava Filter at 224 Days, Lipman, J.; Southern Medical Journal 2805, 98(5), 556-558.

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- Retrieval of the Bard Recovery Filter from a Superior Vene Cava, Rajan, D., et al., J Vasc intery Radiol (2004, 15[10), 169-1171.
 Retrieveble Infertor Vena Cava Filters: Initial Clinical Results, Rosamhal, D., et al.: Annals of Vascular Surgary 2008, 20(1), 157-165.

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PK\$100070 Rev. 4 05/09

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Femoral Vein Approach Instructions for Use



Instructions for Use For use in the Vena Cava

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician,

paysician,

A. General Information

The GZ X Filter is a venous interruption device designed to prevent pulmonary embolism. The unique design and motodist of the GZ X Filter provide littering efficiency and sitow perculaneous placement through a 7 Fenoth (D. Introducer sheath with minimum entry sile difficulties. The placement procedure is quick and simple to perform.

The GZ X Filter is intended to be used in the interior vena cava (IVC) with a diameter less than or equal to 28 mm.

or equal to 26 mm. The Fernoral system allows for placement of the GZ* X Filter via a femoral vein approach. The temoral dictivery system consists of a dilator and introducer set and a delivery device. The dilator accepts a 0.036* guidewine and allows for an 800 ps imaximum pressure contrast power injection. The 46cm, 7 French 1.0. Introducer sheath contains a radiopaque by and harmostates valve with a side port. The flexible nitinol pusher when of the delivery device has a pad at the end of the wire designed to push on the filter apps and a grooved segment is dealigned to hold and properly orient the filter legs. These components secure the filter to the pusher wire as it advances the filter, lip first, to the radiopaque distal end of the introducer sheath, positioned 1 cm below the lowest renal vein. The introducer sheath and delivery device are then pulled back onto the pusher wire handle to unsheathe and release the filter and allow it to recover its predetermined shape. The contenting system sitions the filter and allow it to recover its predetermined shape. The contenting system sitions the GZ* X Filter to be deployed with its retrieval hook centered and minimizes the potential for fegs crossing.

reviews nook centered and minimizes the potential for legs crossing.

The OZ*X Filter is designed to sole as a permanent filter. When oblicially indicated, the GZ*X Filter may be percutaneously removed after implemention according to the instructions provided under the Optional Removal Procedure. The GZ*X Filter's unchors allow the filter to remain rigid and next inflation, but elastically deform when the filter is percutaneously removed. (Reference Optional Procedure for Filter Removal for specific removal instructions).

(Retarence Optional Procedure for Filter Retardant for operative Filters associations). The GZ* X-Filter was determined to be NR-conditional according to the ferminology specified in the American Society for Testing and Malerials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Tesns for Salaty in the Magnetic Responance Environment. ASTM. International, 180 Barr Harbor Cirive, PO Box C700, West Conshotiction, Pennsylvania, 2005.

Non-clinical feeling demonstrated that the GZ^RX Filter is MR Conditional. A patient with this implant can be scenned safety immediately after placement under the following conditions: -static magnetic flate of 3 Feels or less -spatiel gradient magnetic field of 720-Gaess/cm or less -sheaten magnetic fleed of 720-Gaess/cm or less -sheaten m MR system reported whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 institutes of scanning.

In non-clinical testing, the Of" X Fâter produced a temperature rise of 0.6°C at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3-W/kg for 15-minutes of MR acanning in a 3-Total MR system using a transmittreceive body cold (Excite, Software G3.0-0258, General Electric Healthcare, Milweutrea, Wil).

hiR image quality may be compromised if the area of interest is in the exect same area of relatively close to the position of the 62° X Filtor. Therefore, optimization of MR imaging parameters to compensate for the presence of this impant may be necessary.

B. Device Description

The $GZ^{\bullet}X$ Filter System - Fernoral consists of the filter and delivery system. The $GZ^{\bullet}X$ Filter can be delivered via the fernoral and jugular/subclavian approaches. A separate delivery system is available for each approach.

The GET X Fitter consists of twelve shape-memory milited wires emanding from a central relinol steeve with a retrieval hook at the apex of the filter. These twelve wires form two levels of filtration of emboli: the legs provide the lower level of filtration and the arms provide the upper

The GZ* X Filter System - Femoral is illustrated in Figure 1. The delivery system consists of a 7 French LD, latroduces sheath and disator, the GZ* X Filter, a storage tabe with saline infusion port, and a pusher system. The GZ* X Filter is packaged pre-loaded within the delivery storage tabe.

Figure 1: G2* X Filter System - Femoral ŧ,

IMPORTANT: Read instructions carefully before using the G2* X Filter

C. Indications for Use
The GT x Filter. Femoral is indicated for use in the prevention of recurrent pulmonary embotism
via permanent placement in the vena cave in the following stications:
Pulmonery thromboembotism when anticoagulants are contraindicated.
Failure of anticoagulant therapy for thromboembotic disease.
Emergency usestment following massiva pulmonary embotism where anticipated benefits of
conventional therapy are reduced.

- Chronic, recurrent primonary embolism where anticoegulant therapy has failed or is contraindicated.
- GZ X Filter may be removed according to the instructions supplied under Section tabeled: Optional Procedure for Filter Removal.
- D. Contraindications for Use

CAUTION: If the IVC diameter exceeds 26 mm, the filter must not be inserted into the IVC.

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- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.

 Patients with an IVC chameter larger than 28 mm.
- Patients with risk of septic embolism

E. Warnings

- Warnings
 Zfilter implantation
 The GZ X Filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the GZ X Filter cannot be safely reloaded into the storage tube.
 Do not deploy the filter unious IVC has been properly measured.
- Do not deploy use mer unless we have been properly measured.
 Delivery of the GE* X Filter through the introducer should be advance only. Retraction of the pusher wire during delivery could result in dislodgment of the filter, crossing of filter legs or arms, and could prevent the filter from further advancement within the introducer sheath
- introducer sheath.

 The GP X-Filter Femoral is designed for temoral approaches only. Never use the GP X-Filter and Delivery System for superior approaches (jugular, subclavian or entechnitat voin), as this will result in improper GP X-Filter orientation within the IVC. If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot endor filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the goldswire and introducer sheath. Never re-deptoy a removed filter.

 When injecting contrast mediant through the dilator, do not exceed the maximum

- never re-deptoy a removed filter.
 When injecting contrest medium through the dilator, do not exceed the maximum pressure rating of 800 psi.
 Never advance the guidowine or introducer sheathfullator or deploy the filter without fluorescopic guidance.
 Filter fractions are a known compilerable of which the filter without fluorescopic guidance.
- featurescoping questions. Fifter fractures are a known complication of vens cava filters. There have been some reports of serious pulmonary and cardiac complications with vens cava filters requiring the retrieval of the fregment utilizing endovascular and/or surgical
- techniques.

 10. Movement, migration or tilt of the filter are known complications of veria cave filters.

 Migration of filters to the heart or lungs has been reported. There have also been reporte of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.
- 11. Persons with allergic reactions to nickel may suffer an allergic response to this implant.
- After use, the GZ* X Filter and accessories may be a potential blohezerd. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.

See Potential Complications section for further information regarding other known filter complications.

G2 X Filter Romoval

Do not attempt to remove the GT X Filter If significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the year cava well.

NOTE: It is possible that complications such as those described in the "Wardings",
"Procautions", or "Potential Complications" sections of these instructions for Use ma
affect the recoverability of the device and result in the clinician's decision to have the
device namely permanently implanted.

- 2. Never re-dopley a removed filter.
 3. Remove the *GZ* X Filter using an intravascular snare or the *Recovery Const* Removal System only. Refer to the Optional Procedure for Filter Removal section for details.
- PRECAUTIONS

X Fifter Implantation

- This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.
- This device has neither been studied in pregnant women, nor in suprement placement position.

- position. It was instantiated both processes and the prosition and deployment. Careful attention to those instructions for the can shorten insertion time and reduce the fikelihood of difficulties. Position the retrieval hook 1 cm below the towest renal vain. Venacavography must aways be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wait of the IVC, may be misleading. When measuring caval dimensions, consider an engiographic catheler or IntraVascular Utrasound (IVUS) if there is any question about caval morphology. If misplacement, sub-optimal placement, or tilling of the filter occurs, consider immediate removal. Do not attempt to reposition the filter. Retrieva the 02* X Filter using an intravascular sterie or a Recovery Conce* Removal System only. Nater to the Optional Procedum to Filter Removal section to delats.

 Spinal deformations: It is important to exercise care when contemptating implantation in patients with significant hyphosoclotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may make percutaneous removal of the filter more difficult.
- filter more difficult.

 In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrembotic therapy as exon as it is deemed sate.

 It is resistance is encountered during a femoral insention procedure, withdraw the guidewire and chack vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needre and use the vein on the opposite state. A small informations may be bytessed by the guidewire and intenducer.

 In the introducer sheath has a radiopaque distall to cassist in visualization and preciptoyment finter positioning. The radiopaque distall for on the introducer sheath, when used in conjunction with the radiopacity of the pastian wine spine, provides a "target" location abetween which the little should be positioned just prior to unsheathing and deployment.

 Do not attempt to eliabria a syringe or power injection fine to the poximal end of the introducer sheath hub.

 Care should be taken to a nature the connection between the introducer sheath bub and the

- introducer sheath hub.

 12. Care should be taken to ensure the connection between the introducer sheath hub and the filter storage tube is tight; however, the use of excessive force which can cause stippage of the threads arrifor breakage of the hub should be avoided.

 13. It is very important to maintain introducer sheath patiency with the selline flush so that the grooved segment that holds and properly oriants the filter tags does not become covered by clot. This will interfer with filter deptoyment.

 14. Do not deliver the filter by pushing it beyond the end of the Introducer sheath. To achieve proper patement, unsheather the stationary filter by withdrawing the introducer sheath. Do not twist the pusher wire headle at anytime during this procedure.
- Appirating the introducer shaath white leaving the guidewire in place may lead to the introduction of all to the system.

GZ* X Filter Removal

- "X Fitter Removal Analonded veriences may complicate the removel procedure. Careful attention to these Instructions for Use can shorten Insertion time and reduce the likelihood of difficulties. Spinal deformations: It is important to exercise care within contemplating removing the G2" X Fitter to patients with significant hyphosocollotic spinal deformations because the IVC may follow the general course of such analonic deformations. This may requise advanced interventional techniques to remove the filter.
- When using the Recovery Cone* Removal System, the cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered intough the catheter.

NOTE: Standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters (either permanent or rothevable) be tracked and receive "routine (oflow-up" subsequent to the placement of the device.

receive "routine fallow-up" subsequent to the placement of the device.

See Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Oplions Filtors. Milliward S., et al.: J. Vasc Interv Radiol 2005; 16:441-443; Recommended Reporting Standards for Vena Cava Filter Placement and Patient Follow-up. The Participants in the Vena Caval Filter Conference. J Vasc Inter Radiol 2003; 16:5427-5432; Guidelines for the Use of Retrievable and Conventible Vena Cava Filters: Report from the Society of Interventional Radiology Mutifidisciptinary Consensus Conference. Kaulman, J., et al.: J Vasc Interv Radiol 2008; 17:449-459.

G. Potential Complications

- lowing:

 Movement, migration or till of the fiter are known complications of vens cave fitters.
 Movement, migration of till of the fiter are known complications of vens cave fitters.
 Migration of filters to the heart or longs has been reported. There have also been reports of
 caudat migration of the filter. Migration may be caused by placement in IVCs with diamciers
 exceeding the appropriate tabeled dimensions specified in this left. Migration may also be
 caused by improper deployment into clots and/or dislodgement due to large cto: burdens.
 Filter fractures are a known complication of vano cave filters. There have been some reports
 of senous polimonary and cardiac complications with vens cave filters requiring the retrieval
 of the fragment utilizing endovescular and/or surgical techniques.
 Parforation or other acute or chronic damage of the IVC wall.

 Acute or recurrent pulmonery embolism. This has been reported despite filter usage. It is not
 known if thrombi passed through the filter, or originated from suparior or collateral vessels.

- Extravasation of contrast material at time of venacavogram.
- Air embolism
- Hematoma or nerve injury at the puncture site or subsequent retrieval site.
- Hemorrhape
- Restriction of Hond flow
- Occusion of small vessels Distal embolization
- Infection
- Intimal tear
- Sienosis at implant site.
- Fallure of filler expansion/incomplete expansion, insertion site thrombose

- Vessel Injury Arteriorvancus fistula
- Back or ebdominal pain. Filter Tit
- Hemotrorax
- Organ injury Phiographia cerulae doleno Pneumothorex
- Postphiabitic syndrome Stroke
- Thromboohlabilis
- Vennus Literration
- Blood Loss
- Guidewire entrapment

All of the above complications may be associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vents cave filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighted against the interest risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Required

- H. Equipment Required
 The following equipment is required for use:
 One GT X Filter Femoral System that contains:
 One 45 cm, 7 French I D, Infroducer sheelk and dilator set
 One storage tube with pre-loaded GT X Filter and pusher detivery system.
- 0.038" 3 mm J-lipped Guldewire, 110 cm long or longer 18 gauge entry needle

- Contrast madeum
- Starite extension tube for saline drip or syringe for saline infusion.
 All basic materials for venipuncture: scalpsi, #11 blade, local anesitiesia, drapes, etc.

- Directions for Use Insertion of the 7 French introducer Sheath and Preliminary Venography
 Select a suitable femoral venous access rous, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thromboels.
 Prep, drape and enesthetize the skin puncture site in standard fashkon.
- Select and open the carton and outer pouch. Open the introducer sheath and dilator inner
- Nick the skin with a #11 blade and perform veripuncture with an 18-gauge entry needle then the J-tipped guidewire and gently advance it into the distal vena cava or filed vein.

PRECAUTION. If resistance is encountered during a femoral insortion procedure, withdraw the guidawine and check velo patency fluorescopically with a small injection of combast medium. If a large thrombus is demonstrated, remove the verdpuncture needle and fry the velo no the opposite side. A small thrombus may be bypassed by the guidawire and introducer.

Ramove the 18C entry needte over the J-tipped guidewire. Obtain the dilator and the introducer sheath from the package. Flush the dilator and the Introducer with seline. Insert the dilator through the Introducer sheath arsuring that the hubs connect property. Advance the 7-French Introducer sheath together with its tapared dilator over the guidewire and into the distell vena cava or the flac ven.

NOTE: A 0.038" guidawire is used to guida the dilater/introducer assembly beyond the implant site to ensure proper advancement.

PRECAUTION: It is very important to maintain introducer patency with a saline flush to prevent occlusion of the introducer, which may interfere with dalivery device

7. Remove the guidewire and perform a standard Infarior venacovogram (typically 30 mt. of contrast modium at 15mL/s) through the citator. Check for caval thrombi, position of rene) velns, and congenitel enomalies. Select this optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).

NOTE: IVC diameter may be measured using dilator radiopaque marker bands. Marker bands are spaced at a distance of 28mm (outer-to-outer), which references the maximum indicated IVC diameter (Reference Figure 2).



WARNING: When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 800 psi.

WARNING: If the vera cave diameter is greater than 28mm, do not deploy the GZ* X Filter. It large thrombus is present at the initial dolivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an elternate site to deliver the filter. A small thrombus could be bypessed by the guidewire and introducer sheath.

- the filter. A small thrombus could be bypessed by the guidewire and introducer sheem.

 Remove the dilator, leaving the Introducer sheeth with its tip in the distal vene cave or filed valin. Rush intermittently by heard or attach to the introducer sheeth a constant safine drip infusion to maintain latroducer sheeth patiently.

 Advance the introducer sheeth the selected level under fluoroscopic control. The guidewire and dilator should be reinserted to facilitate this. For femoral insertion, the introducer sheeth tip should be 1 cm below the lowest renal vein.

 Open the delivery system knet pouch. Remove the delivery system containing the filer from the package and remove the red safety cap (Reference Figure 3).

Figure 3: Safety Cap Removal # 3

Case 2:15-md-02641-DGC Document 11012-2 Filed 05/07/18 Page 40 of 119 11. Fixes the detvery system with saline through the Y-adapter.

PRECAUTION: It is very important to maintain introducer shouth petency with the saline flush so that the grooved argment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.

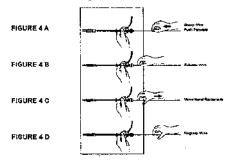
Decome could be seen. This win interfers we make despired in the description.

12. Allich line free end of the filter storage libbe directly to the Introducer sheath already in the vein. The introducer sheath and filter delivery system should be held in a straight line to minimize forcion.

PRECAUTION: Care should be taken to ensure the connection between the introducer sheath hub and the filter storage tube is tight; however, the use of excessive force which can cause slippage of the threads and/or breakage of the hub should be avoided.

13. Looser the Toughy-Borst and advance the filter by moving the ritinol pusher wire forward through the introducer sheetin (Reference Rigure 1 A-D). Do not pull back on the pusher wire, only advance the pusher wire forward.

Figure 4 A-D: Advancement of Filter, illustrated



14. Continue forward movement of the pusher wire until the fitter retrieval hook advances to the radiopaque distel tip of the Introducer sheath. At this point, the black mark on the pusher wire handle should be edjacent to the Y-adapter.

Filter Release/Deployment
15. Deliver and release filter as described in Figure 5 A-C:

Figure 5 A-C: Filter Release, Illustrated

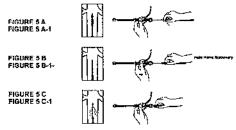


Figure 5 A: Firmly hold the pusher wire handle. Keep this hand stattonary throughout the entire filler release/devicement unboase.

filler release/deployment process.
Figure 3 A-1: Filter positioned at the distall end of the introducer shoath, with the filter retrieval hook, proximal to the introducer radiopaque Up.

PRECAUTION: Do not deliver the filter by pushing it beyond the end of the introducer sheath. To achieve proper placement, unaheathe the stationary filter by withdrawing the introducer sheath as described below. Do not twist the pusher wire handle at anytime

Petition the Alter retrieval hook 1 cm below the towest renal veln
Figure 5 B: With one hand held stationary, the other hand draws the Y-adapter and storage tube
assembly back completely over the handle, encovering and releasing the fifter. Ensure that there
is no stack or bend in the system during the filter retained process. The Y-adapter and
storage tube assembly should be retracted in one smooth, continuous motion.
Figure 5 B-1: Unshresthing of filter in IVC.
Figure 3 C: The position of the hands at the completion of the unsheathing process.
Figure 6 C-1: The filter deployed in the IVC.

16 Now withdraw this pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and incoducer sheath assembly and pulling back on the pusher wire. Do not twist the pusher wire handle at anything during the procedure.
17 Resume the intermittent satine sush or constant ship industron to maintain introducer sheath

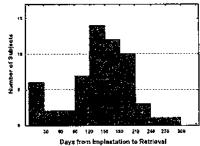
- 17 Resume this intermitient, satine auch or constant any invision to maintain introducer sheating patency.
 Follow-up Venacavogram
 18. A follow-up vanacavogram may be parformed after withdrawing the Introducer sheath into the iliac vein (typically 30mL of contrast medium at 15mL/s).
 19. Remove the introducer sheath and apply routine compression over the puncture sits in the usual way to achieve hampelasse.

OPTIONAL PROCEOURE FOR FILTER REMOVAL:

Clinical Experience
A clinical study involving 100 patients was conducted to assess the safety of removal of the
Q2" X Filter. 61 patients underwant a filter retrieval procedure in which 56 had successful
retrieval of their filter. Of the 42 potents that did not have their filter retrieved, 6 died to unrelated
casess, 3 withdraw, 2 became tost to follow up and 31 were either not clinically indicated for filter
retrieval or failed to meet retrieval eligibility criteria during the period in which the patient could
be considered to filter retrieval per the protocol (within 6 months after filter placement.) The
mean age of the 61 patients who underwant a relatival procedure was 48 years with a range of
19,3416. The indications for filter placement included DVT and/or PE with contributions to
anticoequiation, DVT and/or PE with complication or failure of anticoequiation, and prophylaxis.

The time to retrieval in the 58 patients with successful filter retrievals ranged from 5 to 300 days with a mean of 140 days and median of 144 days. Fileses see the histogram in Pigure 6 depicting the time to retrieval.

Figure 6: Distribution of Filter Indwell Time in Retrieved Subjects



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Removal of G2* X Filter Using an Intravescular Snare

Equipment Required

- One intravascular snare of user's choice
 - One 80-cm Introducer sheath, 7F ID or greater, to be used as retrieval sheath 0.035*3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- Saine
- Contrast medium
- Sterile extension tube for saline drip or syrings for saline infusion. All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc. Procedural Instructions

- Select is suitable juguist venous access route on either the right or tell side depending upon the patient's size or enatomy, operator's preference, or location of venous thrombosis.

 Remove the retrievel sheath from its packaging using sterile technique.
- Prior to use, flush the retrievel sheath with hyperinized sating or suitable isotonic solution. Prepare all other procedure components according to the manufacturers' instructions for Use.
- Use appropriate technique to determine that the filter, the jugular retrieval route, and distal IVC are tree of forombus.
- Select the appropriate toop diameter size of the intravascular snare
- 7. Assemble the intravascular share according to the instructions for Use provided by its
- Insert the guidewire of choice into the retrieval sheath using the guidewire tip-straightener. Gently advance the guidewire into the IVC under fuoroscopic guidence such that it is caudet to the litter
- Introduce and advance the up of the retrieval sheath such that the tip of the sheath is approximately 3cm cephalad to the filter retrieval hook.
- 10. Remove the guidawire.
- 11. Insert and advance the intravascular share assembly through the sheath until it protrudes out of the sheath such that the marker band of the shear catheter is cephalad to the litter retrieval.
- 12. The retrieval of the GT X Fifter using an intravascular snare is (flustrated in Figure 7 A-E:

Figure 7 A-E: Retrieval of G7 X Filter using an Intravascular Spare, Illustrated

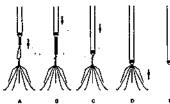


Figure 7 A: Slowly advance the toop forward over the filter spex.

Figure 7 B: Reduce the toop diameter by advancing the snare catheter w
pulling the snare backwards until the loop engages the filter retrieval hook re catheter while simultaneously

NOTE: Ensure that the loop of the snaro has properly engaged the ratileval hook and that the rotineval hook, retrieval catheter and snare are aligned. Be careful to snare the apex of the hook; not the side. The marker Up of the snare catheter must be cephalad to the filter retrieval hook.

NOTE: Always maintain tension on the snare to prevent disengagement of the snare loop from the filter retrieval hook.

Figure 7 C: Advance the sheath in the caudal direction until it aligns with the distal tip of the

steer control.

Figure 7 D: While keeping tension of the snare, hold the retrieval sheath stationary and withdraw the filter into the ratioval sheath by retracting the intervescular aners.

Figure 7 E: Continue retracting the snare until the filter is completely collapsed inside the sheath, once the filter is fully collapsed inside the sheath, retract the complete system as a unil out brough the sheath.

WARNING: Do not attempt to remove the G2^a X Filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the vens cave walk. WARRING: Remove the GZ* X Filter using an intravascular share or the Recovery Cone* Removal System only.

13. Examine the filter to assure that the complete filter has been remo

- 15. Capating the initial to assure met the complete met has been reacted.

 14. A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 m. of contract medium at 15 mls).

 15. Remove the introducer catheter and apply routine compression over the princture site in the usual way to achieve hemostasts.

- usual way to achieve hemostastis.

 Removal of G2" X Filter Using Recovery Cone® Removal System
 Equipment Required

 One Recovery Cone® Removal System that contains:

 -One 75 cm, 10 French I.D. introducer catheter and dilator set

 -One Y-adapter with Recovery Cone® Removal System and gusher delivery system

 0.003" 3 mm J-lipped Guldewire, 110 cm long or tonger

 18 gauge entry needb

 12 French dilator

- Satine
 Contrast medium
 Sterile stantion tube for satine drip or syringe for satire bifusion
 All basic materials for vanipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

If the physician chooses to use the Recovery Cone* Removal System to remove the $G^{\mathcal{P}}X$ Fibral it is available from C. R. Bard, Inc.

retrieval hook

- Procedural Instructions
 Insertion of the Introducer Catheter
 1. Select a suitable jugular venous access route on either the right or left side depending upon
 the patient's size or anatomy, operator's preference, or location of venous thrombosis.
 2. Prep. drape and anesthetize the skin puncture size in standard fishtion
 3. Select and open the Recovery Cone® Removal System package. Open Kit A Introducer

- Select and open ma wedevery come reamoval system package. Open with introducer Catheler package. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle. Insert the guidewire and gently advance it to the bocation of the GZ* X Filter for removal. Remove the venipuncture needla over the guidewire. Pro-filate the accessed vessel with a 12 Franch dilator. Advance the 10 Franch introducer cathelate together with its tapered dilator over the guidewire and into the vole, such that the tip of the sheath is approximately 3cm cephalod to the filter retitional how.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the cathete sheath to assist in visualization.

- 9. Remove the guidowine and dilater, leaving the introducer catheser with its flp in the apprepriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to meintain introducer catheter patency.

 10. Perform a standard interfor venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the filter. If there is significant thrombus within the filter, do not remove the GZ*XFilter.

Case 2:15-md-02641-DGC Document 11012-2 Filed 05/07/18 Page 42 of 119 Recovery Cone® Removal System Insertion and Delivery 11. Remove the Recovery Cone® Removal System and pushes system from Kit B. 12. Flush the central lumber of the cone cetheter and well the cone with estime-preferably hepatratized saline.

- Locsen the Toughy-Boret and slowly withdraw the cone into the Y-adapter to collapse the cone and flush with saline.

PRECAUTION: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered

- the system to war through the catheter. 14. Attach the mate and of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and the retrieval cone system should be held in a straight
- catheter. The introducer catheter and the retrieval cone system should be held in a straight time to minimize findion.

 15. Advance the cone by moving the pusher shelf torward through the introducer catheter, advancing the cone with each forward motion of the pusher shelf.

 16. Continue forward movement of the pusher shelf until the cone advances to the radiopaque marker on the distall end of the introducer catheter. Unaheaths to open the cone by stabilizing the pusher shaft and extracting the introducer catheter.

 17. The retrieval of the GZ* X Filter using a Recovery Cone® Removal System is illustrated in

Figure 8.A-E: Retrieval of G2* X.Filter using Recovery Cone* Removal System, Illustrated

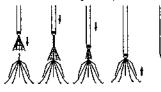


Figure 8 A: After the cone has been opened superior to the filter, carefully advance the cone over the retrieval flock by holding the introducer catheler stationary and advancing the pushes shott. It is recommended to obtain an anterior-obtique fluoroscopic linega to conflim that the cone is over the retrieval hock.

Figure 8 8: Close the cone over the retrieval hock by advancing the introducer catheler over the cone while holding the pusher shaft stationary.

Figure 8 0: Continue advancing the Introducer cetheter over the cone until the cone is within the introducer catheler.

Introducer carriers by Williams cone collapsed over the filter, remove the filter by stablishing the introducer catheter and retracting the pusher shalf in one, smooth, continuous motion. Figure 8 E. The filter has been retracted into the estheter.

WARNING: Do not attempt to remove the G2* X Filter If significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the vene cava wall.

WARNING: Remove the ${\cal Q}^{\bullet}$ X Filter using an intravascular snare or the Recovery Cone Removal System only.

NOTE: It is recommended to fluoroscopically image the filter in AP and lateral views during retrieval.

NOTE: If difficulty is encountered while attempting to engage the retrieval hook and/ or multiple passes are required, consider using an introvoccior enere as an atternate retrieval method.

18. Examine the filter to assure that the complete filter has been removed

Follow-up Vanacavogram

- A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mUs).
 Remove the Introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guidewire - Assisted Technique

Due to anatomical variances with respect to the position of the $G2^{\bullet}$ X Fitter guidewire-assisted techniques may be used.

tise of a Guidewire

Use of a Guidewire.

It is difficult to align the cone with the GZ* X Fifter retrieval hook, one may use a guidewire to facilitate advancement of cone over the retrieval hook. The facilitate advancement of cone over the retrieval hook. Insert a 0.035* 260 cm guidewire through the central turnen (a stiff guidewire with J or angled tip is recommended). Advance the guidewire timough the cone and shrough the falter near the retrieval hook. After I have been confirmed that the guidewire is no contact with or in close proximity to the retrieval hook, advance the cone over the guidewire to the retrieval hook. Advance the cone-best hook is the falter of the retrieval hook. Withdraw the guidewire into the pusher shaft. Continue removing the Fifter as described in step 17.

J. How Supplied

Each GZ* X Filter is supplied preloaded in a storage tube. Each GZ* X Filter is sterile and nondyroganic unless the package is damaged or opened, and is ready for single use only. The storage tube and detivery system are pre-assembled. If the filter is inadvertently discharged, do not attempt to re-stellitize or reload it.

WARNING: After use, the GZ* X Filter and accessories may be a potential biohazard. Nandle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The GZ X filter should be stored in a coot (room temperature), dark, dry place

K. Warranty

N. Werranty Bend Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in malerials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your not price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warrantles, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

An issue or revision date and a revision number for these instructions are included for the user's An isset of revisition date and a present interior in the reset absolutions are included in the user information on the last page of this bookide. In the event 36 months have elapsed between this date and product use, the user should contact Sard Peripheral Vascular to see if additional product Information is available.

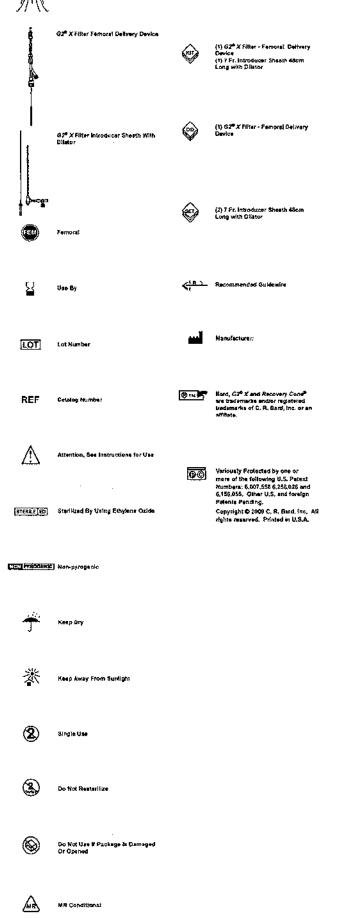
For additional vens cave filter clinical information please refer to the following societal guidelines:

- "Practice Guideline for the Performance of Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Fulmonary Embolism" [ACR Practice Guideline 2007: 38:673-684)
- seror-besj
 "American College of Chest Physicians: Opinions regerding the diagnosis and
 management of vaneus thromboembolic disease. ACCP Consensus Committee on
 Pulmonery Embolism. American College of Chest Physicians" [Chest 1998 Feb; 113(2): 499-5041
- 499-594
 "Practice Management Guidalines for the Prevention of Venous Thromboembolism in Trauma Patients: The EAST Practice Management Guidalines Work Group" [J Trauma 2002; 55:442-614]
 "Quality improvement Guidalines for Percutaneous Inferior Vene Cave Filter Placement for the Prevention of Pulmonary Embolism" [JVR 2003; 14:S274-S275]

 Ottally Improvement Guidežnes for Percutaneous Permanent Infatior Vena Cava Filter Placement for the Prevention of Pulmonary Emboism, Grass, Swan, Cardella, et al.: J Vesc (1997) 1997 (1997) 1997 (1997) 1997 Inlary Radiol 2003; 14:S271-S275.

Case 2:15-md-02641-DGC Document 11012-2 Filed 05/07/18 Page 43 of 119 Radiology 2002, 225(3), 835-844. 3. Retrievability of the Recovery Vena Cava Filter After Dwell Times Longer Item 180 Days. Blinkert, C., et al.: J Vasc their Radiol 2006, 17(2), 299-302. 4. Experience with the Recovery Filter as a Retrievable inferior Vena Cava Filter. Grande, J., et al.: J Vasc Interv Radiol 2005, 16(9), 1189-1193. 5. Difficult Retrieval of a Recovery IVC Filter. Hegspel, K., et al.: J Vasc Interv Radiol 2004, 15(6), 645-647. 6. Removal of Vena Cava Filter at 224 Days. Lipman, J.: Southern Medical Journel 2005, 98(5), 556-558. 7. Retrieval of the Bard Recovery Filter time a Superior Vena Cava Raiso, D. M. al.: J Vasc.

- S56-558.
 Retrieval of the Bard Recovery Filter from a Superior Vena Cava Rajan, D., et al.; J Vasc talery Radiol 2004, 15(19), 1169-117 1.
 Retrievable Infector Vena Cava Filters: Initial Clinical Results. Rosenthal, D., et al.: Annats of Vascular Surgery 2006, 20(1), 157-165.





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PK5100059 Rev 4 08/09



G2.

What's New

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Search





The G2[®] Filter quickly established its exceptional performance as a permanent yena cava filter with over 65,000 units sold worldwide

NOW WITH THE OPTION OF EXTENDED RETRIEVAL, the G2® Filter gives physicians complete control over their patients' care.

- Increased MIGRATION RESISTANCE*
- . IMPROVED CENTERING
- Enhanced FRACTURE RESISTANCE*
 - · Data on File

Clot Trapping and Caval Patency

G2[®] Filter utilizes the proven conical filter shape arranged into two offset layers that effectively trap large and small emboli without compromising caval patency.

Secure Fixation

Now featuring a wider leg span and thicker fixation hooks, the newly enhanced G2® Filter resists migration across an even broader range of caval distension and higher pressures.*

* Maximum indicated caval diameter is 28 mm. Data on File



Easy to Use

Filter is completely loaded into the delivery system for easy assembly and delivery

Self-Centering

Specially designed pusher wire and articulated arms promote a centered filter placement, even through fortuous anatomy.

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G2™ Filter System



Timeless Performance

NOW AVAILABLE - JUGULAR DELIVERY SYSTEM



The G2⁻⁻ Filter combines the best design features of Bard's existing vena cava filters to create a brand-new permanent filter platform — taking strength and stability to a new level.

The newly enhanced G2" Filter continues the Bard tradition of filter innovation spanning over a decade.

- Increased MIGRATION RESISTANCE*
- . IMPROVED CENTERING
- Enhanced FRACTURE RESISTANCE
- * Data on File

Clot Trapping and Caval Patency

G2⁷⁶ Filter utilizes the proven conical filter shape arranged into two offset layers that effectively trap large and small emboli without compromising caval patency.

Secure Fixation

Now featuring a wider leg span and thicker fixation hooks, the newly enhanced $G2^\infty$ Filter resists migration across an even broader range of caval distension and higher pressures.*

* Maximum indicated caval thameter is 78 non. Data on File



Low-Profile

7F delivery system is the lowest profile of any conical filter on the market.

Self-Centering

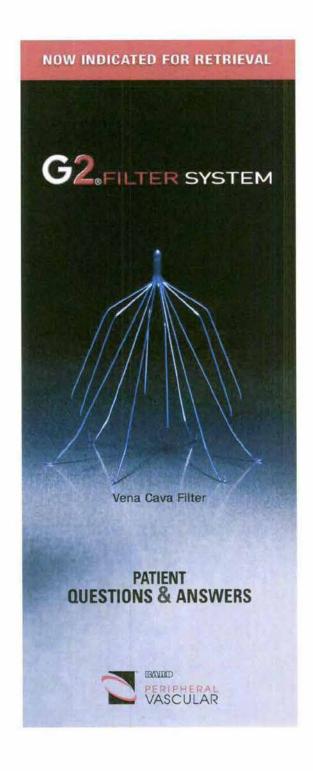
Specially designed pusher wire and articulated arms promote a centered litter placement, even through tortuous anatomy.

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The safety and effectiveness of the G2 Filter System for use as a noticeable or temporary filter have not been established.

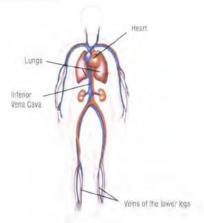
Please consult product liabels and prackage moons for indications, continensications, hazards, warnings, castions, and information far asset Bard and Trimeless Performance are registered trademarks of C. R. Barst, inc. of an affiliate. Q2 is a trademark of C. R. Bard, Inc. or an affiliate. Copyright 6 2008. C. R. Bard, Inc. All Rights Reserved.





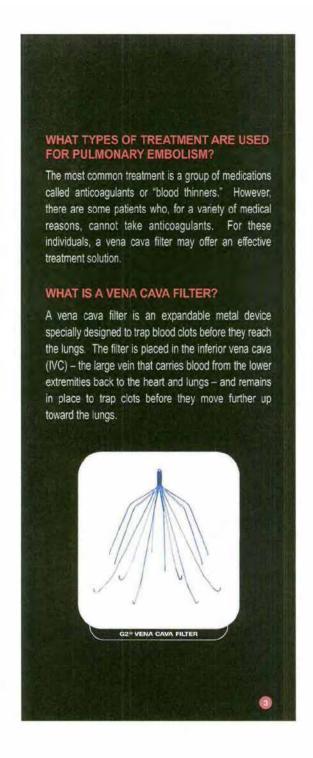
PULMONARY EMBOLISM AND VENA CAVA FILTERS

Your doctor has given you this booklet to help you learn more about pulmonary embolism — what causes it, how it can affect your body and, most important, how it can be treated. After reading the booklet, talk to your doctor about any questions you have. It's important to remember that each patient is different and that only your doctor can give you information about the details of your specific treatment.



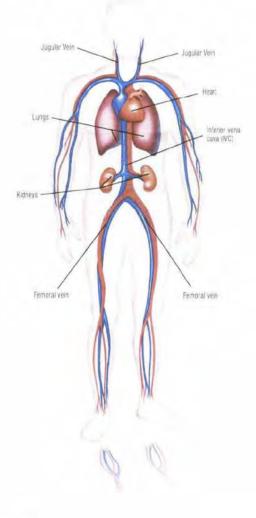
WHAT IS PULMONARY EMBOLISM AND WHAT CAUSES IT?

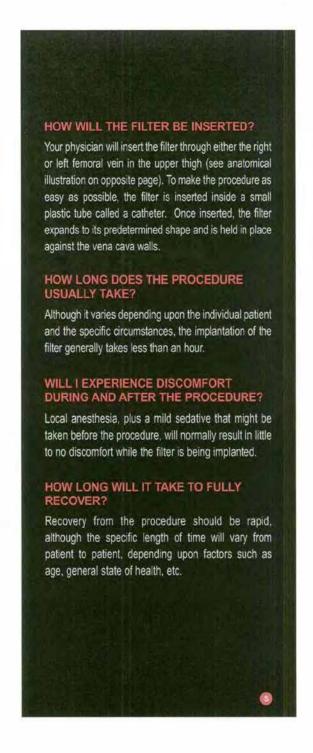
Pulmonary embolism is the condition that results when a blood clot forms, usually in the deep veins of the lower leg, and becomes loosened, traveling upward from the legs in the bloodstream. If left untreated, there is a possibility that the clot may move up into the arteries that carry blood to the lungs. If this occurs, the normal functioning of the lungs may be impaired.



THE IMPLANT PROCEDURE

The anatomical sites identified below will provide general guidance on those areas that are important in an implant procedure.





AFTER THE PROCEDURE

HOW LONG WILL THE FILTER LAST?

The $G2^{\epsilon}$ Filter is designed to be a permanent implant and will not need to be removed, repositioned, or replaced.

CAN THE FILTER BECOME CLOGGED?

In the great majority of cases, the answer is "no." Once a clot becomes entrapped in the filter, the normal flow of your blood through the vena cava and the filter will usually dissolve a trapped clot as the blood flows over it.

IF I SHOULD NEED AN MRI EXAM, WILL THE METAL FILTER INTERFERE WITH THE TEST?

The G2^E Filter is made from an alloy of nickei and titanium, and will not interfere with the test.

UNDER WHAT CIRCUMSTANCES SHOULD CONTACT THE DOCTOR RIGHT AWAY?

You should contact your physician right away if you experience any of the following:

- sudden onset of chest pain accompanied by shortness of breath
- · swelling in both egs
- · unexplained pain in the abdomen

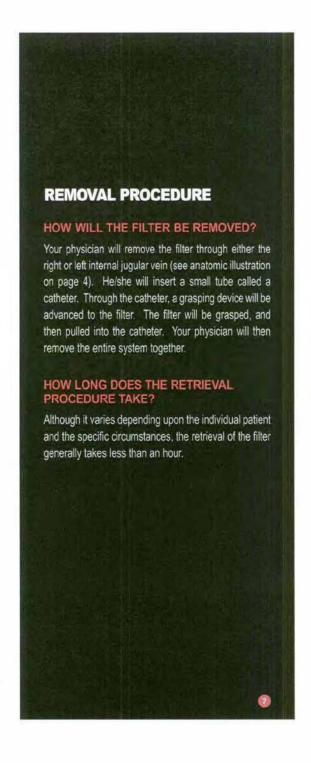
CAN THE FILTER BE REMOVED?

Yes. The filter can be removed when your physician determines that you no longer need it.

WHEN CAN THE FILTER BE REMOVED? IS THERE A "CUTOFF DATE" BY WHICH THE FILTER MUST BE REMOVED?

The 62* Filter does not have a time limit in which it must be removed. The filter can be removed at any time after the point at which you no longer need it. This is up to your physician.





LMD1

WILL I EXPERIENCE DISCOMFORT DURING AND AFTER THE PROCEDURE?

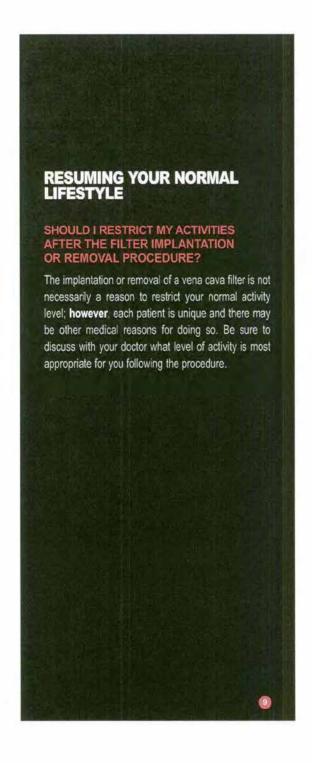
As with the implant procedure, local anesthesia, helped by a mild sedative given before the procedure, will normally result in little to no discomfort while the filter is being removed. Afterwards, you may experience mild soreness in your neck for a few days. This is normal and will disappear. You will be left with a small scar on your neck at the puncture site.

HOW LONG WILL IT TAKE TO FULLY RECOVER FROM THE REMOVAL PROCEDURE?

Recovery from the removal procedure should be rapid, although the specific length of time will vary from patient to patient, depending upon factors such as age, general state of health, etc. Typically, you will be discharged several (2-3) hours after the procedure.

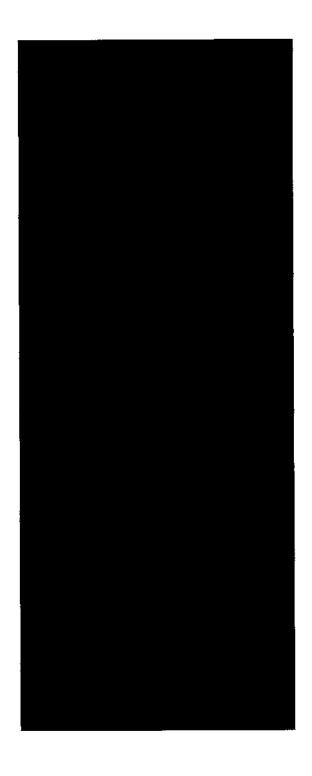
DOES THE FILTER HAVE TO BE REMOVED?

No. The G2⁵ Filter is designed to be a permanent implant and does not have to be removed, repositioned, or replaced.



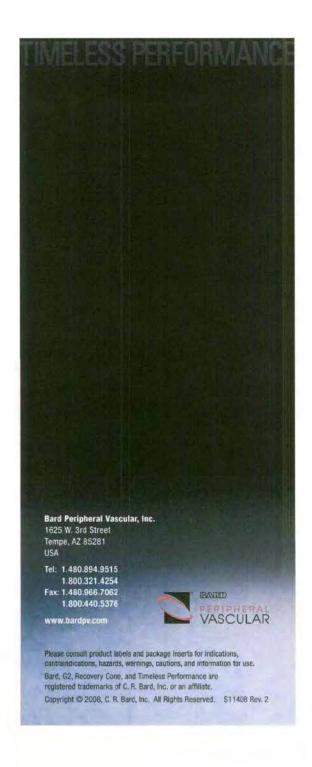
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Filter System

G2[®] Filter System Jugular/Subclavian Veln Approach Instructions for Use



Instructions for Use

For use in the Vena Cava

Caution: Fodoral (U.S.A.) law restricts this device to sale by or on the order of a physician.

The GZ^a Filter represents a new generation of venous interruption devices designed to prevent pulmonary embosism. The unique design and material of the GZ^a Filter provides thering efficiency and allow percutaneous placement through an angiographic whiteduces with minimum entry size difficulties. The placement procedure is quick and

The G2* Filter is intended to be used in the inferior vens cays (NC) with a dismeter less than or equal to 25 mm The GF Filter is inhanded to be used in the inflorer venu cave (NC) with a dishnator was than an expension. The liguistration processing the advantage of the processing of the GF Firer via a jugical or restolation with approach. The injuriate studies and although a studies and inhand the studies of dishnay dishner. The distort accepts a 0.037 guidewire and allows for an 800 pat maximum pressure contrast power injection. The 16 Financia III. Institution sheath contrasts a cardiopeque by and hermostasis valve with a size part. The detivery device is within the introducer sheath and convists of a stife port for saline inferior and a derivery mechanism to deploy the GF filter. The delivery device contains a spiline capital mechanism to deploy the GF filter. The delivery device contains a spiline capital mechanism for the stifer hoots from one another for a unique pattern to prevent leg entengiement. The GF filter is presented within the delivery device. Once the introducer sheath is winted to certain the delivers and delivery the temporary and the introducers and delivery that the contraducers and delivery that the contraducers and delivery that the contraducers are defined and the introducers and delivery that the contraducers are the mediate contraducers. with position, the delivery daytee is advanced through the introducer sheath antil the introducer and delivery

wants personal, the bearing values is devanted attended. The introducer that is pulled back over the pusher with handle to unsheaths and refeate the GZP-filter following if to recover to its predefermined shape. The filter following if to recover to its predefermined shape. The GZP Filter is designed to act as a permanent feter. When clinically indicated, the GZP Filter may be persultaneously removed after inspleations recording to the instructions provided under the Optional Removal Proceedure. The G2* Fitters elegac hooks allow the filter to remain rigid and resist magnetion, but elasticatly deform when the filter is percuraneously removed. (Raference Optional Procedure for Filter Removal for specific removal instructions.)

Non-cinical tasting has demonstrated their the GZ* Filter is MR Conditional. It can be scanned solely under the following conditions:

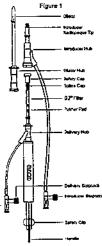
- ing consilisons: Static Magnatic field of 1 6-Testo et less. Spatial grastent field of 450 Gaussicm et less Maximum whole-body-everaged specific absorption rate (SAR) of 1,5 Witig for 20 mountes of scanning. non-chines recommenced where the produced a temperature rise of less than or equal to 0.8°C at a maximum who non-chines testing the DP filter produced a temperature rise of less than or equal to 0.8°C at a maximum who year equal specific absorption rate (SAR) of 1,5 W/kg for 20 munutes of MR scanning up a 1,5 Tasia, General ection Headthcore MR scannar.

MR Image quality may be compounted if the area of interest is in the exact same area or relatively close to the person of the GPS First Therefore, it may be necessary to optimize MR imaging parameters for this presence of this metallo kinglant.

8. Device Description

The GZ* Fifter-Juguise/Subclavian System consists of the fifter and delivery system. The GZ* Fifter can be delivered via the femoral and liguist's bolevian approaches. A separate colivery system is available to: each approach. The G_{α}^{p} Fider consists of twelve shape-memory nitact wires extensiving from a cantad attact steam. These twolve wise form two levels of filtration of embot, the legs provide the lower level of filtration and the arms provide the upper level of literation.

the GZ* Filler System Jagulan/Subclavien is likistrated in Figure 1. The Oathory System consists of a 10 French (C. notoducer theath and offetor, the GZ* Friter, and a delivery cavice. The GZ* Fitter is peckaged pre-foeded within the delivery device.



(MPORTANT: Road Instructions corefully before using the G2*Falter

C. Indications for Use

The G2º Fitter System-Jugulan Subclevian is indicated for use in the prevention of recurrent pulmonery embolism via permanent piecement in the vene cave in the following a fuetrors:

- Pulmonary thremboembolism when enticongulants are containdicated. Felture of enticongulant thereby for thromboembolic disease.
- Emergency treatment following massive pulmonary embellain where anticipated benefits of conventional therapy
- Chronic, recurrent pulmonary embelism where enticoegular: therapy has falled or is controlled cated
- GZ* Filter may be removed according to the instructions susplied under Section labeled: Optional Procedure for Filter Romaval.

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

The GZ® Exter should not be implanted in:

- Pregnant gatents when fluoroscopy may endenger the fatus. Risks and benefits should be assessed carefully. Patients with an IVC diameter larger than 28 flux. Patients with risk of septic embolism.
- E. Warnings

- The 62 Filter is pre-incided and is intended for single use only. Do not deploy the filter prior to prope
- The GPF Filter is pre-loaded and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVO, as it the CPF filter cannot be safely reloaded. Do not deploy the filter unless IVC has been properly measured. (Refer to Proceution # 4), it large thrombus is present in the initial debloyer site, do not attempt to deliver the filter. Migration of the clost ancider filter may occur. Select an afternate site to deliver the filter. A small thrombus could be hypasted by the guidewire and introducer sheafth.

 Only use the Recovery Cores* Removal System to remove the GP* Filter. Never re-deploy a removed defined.
- Never advance the guidewire or introducer sheath/dilator or deploy the filter without fluoroecopic guid-
- since.

 Fifth fractures are a known complication of verisions exist filters. There have been some reports of serious pulmonary and cardiac complications with verisional filters requiring the retrieval of the fragment utilizating endovascular and/or surgival bachinques.

 Movement, importance of the filter are known complications of verisionary filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter, Migration may be caused by priscentant in NOs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots another distogenest due to large clot burdens.

 Never use the lugister or subclavian delivery system for lemonal approach, as this will result in improper Q2° filter orientation within the IVC.

 When allocition contract medium through the distort on not exceed the maximum pressure rating of 800.
- When injecting contrast medium through the dilator, so not exceed the maximum pressure rating of 800

(1)

Reference Potential Complications section for further information regarding other known filter complica-

- Do not attempt to remove the G2* Filter if significant amounts of thrombus are trapped within the After or it the filter tip is embedded within the vena cavat wait.
 NOTE: R is possible that complications such as those described in the "Warnings", "Precautions".
 - or "Potential Complications" sections of this instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implented
- Use only the Bare Receivery Const Removal System (packaged separately) to retrieve the G2* Filter. Use of other removal devices has medited in recurrent pulmonary embellam.
- Never re-deploy a removed filter.

F. Preceutions

G2^e Filter Implentation

- 1. This product is intended for use by physicians trained and experienced in diagnostic and interventional lect-
- This device has neither been studied in pregnent women, nor in suprerenal placement position. 1
- Anatomical variences may come source as programmer was entired in apprehensive partyrament positions. Anatomical variences may complicate foliar haselton and deployment. Caseful attention to those instead Use can shorten insertion time and reduce the Exchange of difficulties.
- use on a control membros arise and results the Listangou of all customs.

 Position the filter the 5 cm below the lowest send vein. Venezongraphy drust always be performed to confirm proper implant site. Redographs without contrast, which do not clearly show the wall of the IVC, may be min-
- When measuring caval dimensions, consider an anglographic catheter of IntroVascular Ultrasound (IVUS) if there is any quastion about caval merphology
- thate's any quasion about cave morphology. It may be considered the properties of the fits occurs, consider immediate removal. Do not attempt to reposition mather, Retrieva the Gz* Filter using the Recovery Conse* Removal System Ordy. Refer to Optional Procedure for Fitter Removal for details. Spend deformational: it is important to exercise some when continuing implemation in patients with significant xyphocoologic plant of continuing the procedure of such enatures the IVO may follow the general course of such enatures deformations. This may make precisions or entired of the filter more difficult.
- in parema with continues disk of chronic, recurrent pulmonary embolism, patients should be returned to entithrombotic therepy as soon as a is deemed less.
 If reastance is excountered during the invention procedure, withdraw the guidewire and check vain patency fluo-
- teacopically wish a small injection of contrast medium. If a large thrombus is present, remove the venipuncture needs and use the venipuncture of the venipuncture of
- Ensure that the introducer and the delivery device hubs are snapped logisther and that the system has been
 positioned for optimal placement. Selece deploying the GZ* Stat.
- Do not remove the selety city cuts the findoucer and the desirery device hubs are snapped together.
 On not deliver the filter by pushing on the handle, rather related the introducer hub to properly deploy the G2**
- tills wery important to mainteun introduces potency with a settle firsh to provent occlusion of the introduces, which may interfere with delivery device advancement. 13. It is very imp
- 54. Aspirating the introducer sheath while leaving the guidewire in place may lead to the introduction of air into the system.

G2⁶ Fifter Removal

- Anatomical variances may complicate insertion and deployment of the Recovery Conce Removal System.
 Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of difficult.
- Ceremi insustron to maps imparticular to detect an another insection and account on a measured on institute Spiral deformations: it as important to excelled care when contempleting removing the d2st Fillar with the Recovery Coord Removel System in patients with significant hyphosociatic spinal deformations because the WC may follow the governal courtee of such anatomic deformations. This may require advanced interventional techniques to remove the filler.
- Remove the G2*Cast using the Renovery Cone* Removal System Only Reter to the Optional Procedure for Filte: Removal section for details.

 The cone must be fully refracted into the Y-edepter before connecting the system to the introducer contraint to

assign that the cone can be properly delivered through the cetheter.

Note: Standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters (other permanent or reintervable) be tracked and receive "routine follow-up" subsequent to the placement of the device

to the placement of the device to the caval Filter Placement and Patient follow-up: Supplement for See Reporting Standards for Interior Vene Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters. Milkward, 8., et al.: J. Vasc Interv Radiol 2005; (8:441-445); Recommended Reporting Standards for Vene Caval Filter (Jacement and Patient Follows). The Patiticipants in the Vene Caval Filter Consensus Continence: J Vasc Inter Radiol 2003; 14:3427-5432; Guidelines for The Use of Retrievable and Convertible Veno Cava Fitters: Report from the Society of Interventional Radiology Mukidsolpilinary Consensus Conference. Kaufman, J., et al.: J Vasc Interv Radiol 2008; 17:449 489.

Procedures requiring percurencous interventional techniques should not be aziempted by physicians unternitiar with the possible complications. Complications may occur at any time during or after the procedural Possible complications include, but are not braited to, the following:

- Movement, migration or still of the fifter are known complications of vene cave fifters. Migration of fifters to the head or hungs has been reported. There have also been reports of excisal migration of the fifter. Migration may be created by placemental VICA with disamples exceeding the suppropriets labeled disampless respected on that IFU. Migration may also be caused by improper deployment, deployment into clots and/or distodgement due to
- Filter haptures are a known compression of years cave filters. There have been some reports of serious pulmonary and certure complications with vene cave filters requiring the retrievel of the tragment utilizing endous and/or engligation injured in a manage of the IVC well.

 Acute or recurrent pulmonary embellarm. This has been reported despite filter usage. It is not known it detemble
- passed through the filter, or originated from superior or collateral vessels. Deep velo thrombosis
- Cavet thrombosis/occlusion.
- Extravasation of contrast material at time of variacsvogram
- Air embelism.
- · Herratoma or nerve injury at the puncture alle or subsequent retneval site.
- Hamenhage.
- · Restriction of blood flow
- Occlusion of small vessels. Ontal embolization
- (milms) tear
- Stanceis et implant sile.
- Fathers of filler expansion/incomplete expansion
- · Insultion site thrombosis
- Vessel injury Arteriovenous fistula
- Sack or abdominal pain
- · Fitter tilt
- Hemothox
- Oronn infury
- Pnjegmesus cerules dolons
- Pneumotherex
- Postphlebitic syndrome Stroke
- · Thrombookebitis
- · Scoot less
- Pain

Case 2:15-md-02641-DGC Delta in the above compile share large began argued to perform refree event that the product of the control of the co

weighed against the Inherent risk/benefit ratio for a patient who is at clek of pulmonary embolism without Intervention.

K. Equipment Required

- One GZ⁶ Filter Jugular/Subdaylan System that contains: One 55 cm, 10 French I.D. introduces and dilator set
- One delivery device with pre-loaded G2° Filter 0,038° 3 mm 3-tapped Guidewire, 110 cm long of longer 18G entry needle

- Stellé extension tube for saline dip or syrings for sellne infusion
 All basic materials for vanipuncture: sosipes, étà blade, local anasthosia, drapas, etc.

If the physician chooses to perchanguisty remove the GS[®] Filter, the Recovery Conv[®] Removel System is available from C. R. Bard, Inc.

1. Directions for Use

- Select a switzbis jugutar or subclavian venous access muta, on either the right or tell side, depending upon the patient's size/anatomy, operator's preference, or location of venous thromboss.

 Prep, drape, and amerijhetz

- Nick the skin with a #11 blade and cerform verious cture with an 18G entry needle
- finant a 1-tipped guidewise and gently advance it toto the inferior vana cave

PRECAUTION: It resistance is encountered during the insertion procedure, withdraw the guidewire and check velo patency fluorescopically with a small injection of contrast medium. If a large thrombus is present, remove the employmenture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidawire and introducer.

Remove the 18G entry needle over the 3-tipped guidawire. Obtain the distor and the introducer sheath from the peckage. Evan the distor and the introducer with cohen, tenden the distor though the introducer sheath ensuding that the hubb scale logether. Advance in a CFFrench introducer heath logether with its tapered distor over the guidawire and into the interior years cave.

งารแรงช ยูงพองหาย and into the intensy vana cave. NOTE: A 9.038" guidewine is used to guide the dileter/introducer sessibly boyand the implant elfo to epsure proper advancement. PRECAUTION: It is very important to maintain introducer patency with a sating flush to prevent occurring of

the introducer, which may interfere with dollvery device advancement.

7. Parform a standard Inferior varacevoguem (typically 30 ret, of contrast medium at 15mt/s) through the dilator.

Check for cavel brombi, sociátin of renel veins, and congenital snormáres. Select the optimum level for Riter
placement and measure of the VEO demekts, consisting for regulification (typically ZD) personally.

WARMING: When injecting contrast medium through the distor, do not exceed the maximu

WARNING; if the wens cave dismeter is greater then 28mm, do not deploy the G2* Filter. It targe thrombus is present at the initial delivery site, do not attempt to deliver the filter. Alignation of the clot and/or filter may octur. Select an ellernate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introduces sheeth.

Separate that drains and inlendance hubs by banding and that pulsing apart (Reference Figure 21. Remova the guidewise and didetor, leaving the 10 French introducer sheath with its tip in the intenor vene cave. Flush intermetently by hand or attack to the introducer stopock a constant salise displusion to maintain introducer



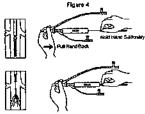
Remove the delivery device from the package and remove the red safety cap (Reference Figure 3).



- Flush the delivery device with seline through the delivery stopcock.
 Insert and advance the delivery device through the introducer sheeth until the introducer and delivery device. hubs snap logetter (Reference Figure 4)

PRECAUTION: Ensure that the introducer and the delivery device hubs are enapped together and that the system has been positioned for optimal placement, before deploying the G2* filter.

NOTE: Do not remove the eafety clip until step #13.



12. Under Rucroscopic control position the system to optimal placement. The distant and of the purifier pad provides the radiopaque indicator for positioning purposes (Relevance Figure 5). NOTE: Bo not remove the safety clip until step #33.



NOTE: A gep between the filter spea and pusher pad is normal.

- 13. Remove the satety clip from the delivery device
- Stabilize the handle and out back on the inhoducer hub (blue) to retract both the introducer sheath and delive ony device. Retract the introducer hub until line handle bettoms out against the proximpt edge of the delivery controtor hub (white). This will referee this Q2® floor into position (Reference Figure 6).

RRECAUTION: Do not delive: the filter by pushing on the handle, rather retract the introducer hub to property deploy the $G2^{\sigma}$ filter.



- Separate the delivery and introducer hote by beauting and then pulling epen. Retrict and remove the delivery device from the introducer sheeth.
- Perform a venecevogram to confirm satisfactory deployment before terminating the procedure
- Remove the introducer sheads and apply routine compression over the procture into in the usual manner to

CAUTION: Remove the G2[®] Filter using the Recovery Cone® Removal System only.

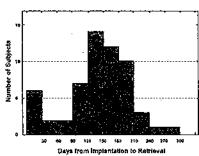
Removal of G2º Fifter

- 18 gauge only needle 12 French dietor
- Saline
- Contrast medium
- Statile expession tube for selfae drip or syninge for selfine infusion.
 All basic materials for venipuncture; scalpel, \$11 blade, local apasthesis, drapes, atc

Canical Experience

A chizcal study involving 100 patients was conducted to excess the safety of removal of the G2* Filler. 81 patients underwent a fiber relatival procedure in which 55 and successful midrated of their filler. Of the 42 patients that did not shave their fitter received, 6 did of unrestated causes, 3 withdraw, 2 became text to follow up and 31 were either not strike stylind causes of their received. 6 did of unrestated causes, 3 withdraw, 2 became text to follow up and 31 were either not strike stylind causes of their received parts and the strike stylind causes of their received parts and the strike stylind causes of the stylind cause of the stylind cause of the stylind causes of the stylind cause of the stylind cause

Sigure 7: Distribution of Filter Indwell Time in Retrieved Subjects



Of the 61 attempted filter retrievals, 3 technics: fallures for retrieval resulted from instrity to engage the filter apex With the Recovery' Contrel Renate Jestimos deaders on features tracked soft interest to engage the interest personal tracking of the filter spex into the vene covariance. One of the 55 successful filter efficients two-lived in fact that was retrieved in spite of this and associated ambedding of filter spex into covariance.

ung ur imm apek underviews.
There was an aymptomatic complication in the study. A pelleri, reported low back poin later a successful filter place-ment. On pre-etifievel imaging, two (2) of the filter arms were found to be penezoling the cavel wai. The filter was successfully referred and the pair resolved.

Asymptomitic complications included caudid ingretion (n=10), fracture (n=1), IPE (n=2), filter lift (n=15), penelvation (n=1), and cavel stendard (n=1), non-occlusive cavel thrombods (n=1), and cavel stendard extended in the post successful ferrorated (n=1).

Procedural Instructions

- Procedural instructions
 Interction of the Introducer Catheter

 1. Select a suitable jugular vanous access rusie on either the right of left side depending upon the patient's size or a nature, operator's preference, or location of venous (nuombosis

 2. Prep, drace and americate the skin puncture attain abnitised fraction.
- Select and open the Recovery Came® Removal System spackage. Open Kit A Inboducer Cathelor package hids the skin with a #11 blade and perform vanigumstore with an 18-gauge entry needle. Insert the guidentice and gently advance if to the location of the GZ® Filter for removal.

- Remove the variguactive needs over the guideview.

 Remove the variguactive needs over the guideview.

 Remove the variguactive needs over the guideview.

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 Remove the variguactive needs over the guideview and into the vert.

 NOTE: The introducer catheter has a participactive marker at the distallent of the catheter sheath to sesse in
- Remove the guidewise and dilater, leaving the introducer cuthator with its to in the appropriate location. Flush interestedily by head or effect to (the catheter a constant seited drip tohision to maintain introducer catheter pat-
- Perform a standard enterior vanacewognem (typically 30 mt, of controst modium at 15 mt/s). Check for thrombus within the filter, if there is significant thrombus within the filter, if there is significant thrombus within the filter, of onot remove the GZ* Filter.

- Recovery Cone® Removal System Insertion and Dollvery

 11. Recover the Recovery Cone® Removal System and pusher system from Kd B.

 12. Flush the central lumes of the cone catheter and wet the cone with salls—great

14. Fram the central library theonome canness and well not coles who saline—greenably superinced saline.

19. Slowly withdraw the cone into the Y-adaptor loc collapse the code and flut, whis saline,

PRECAUTION. The cone shurt be fully retracted into the Y-adaptor before connecting the system to the introducer catheler to ensure that the cone can be properly delivered through the catheler.

14. Affect his marie and of the Y-adaptor with the collapsed cone directly to the unforded catheler. The inheducer catheler and lifter delivery system should be held in a straight limb to infalmize directly.

15. Advance the cone by moving the puebles shalf to ward through the infroducer catheler, advancing the cone with each forward motion of the puebler shalf.

- 16. Continue (owned movement of the pusher sheft until the cone advances to the redopaque injuster on the distell end of the introducer catheter. Unsheaths to open the cone by stabilizing the gusher sheft end retracting the

Capture of GZ® Filter Filter Removal, filestr

17. The capture of the GZ* Filter is illustrated in Figures A-E.

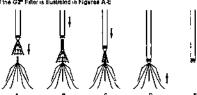


Figure A: After the coan has been operand experior to the filler advance the cone over the titler tip by holding the inhoducer catheter stationery and advancing the pusher shaft. It is recommended to obtain an axtenor-obtaine theoretic plant in the cone is over the filter to. Pigure B: Close the cone over the filter bip by advancing the inhoducer catheter over the cone while holding the pusher shaft stationary. Figure C: Continue advancing the introducer catheter over the cone is within the inhoducer catheter. Figure D: With the cone collegeed over the filter, remove the filter by stabilizing the introducer catheter and vatracting the guiser's shaft in one, smooth, continuous motion.

Figure E: The fitter has been retracted into the catheter.

10. Examine the filter to example that the complete filter has been removed.

- Remove the introducer catheter and apply routine compression over the puncture are in the visual way to

Guldewire - Assisted Technique

Due to analomical variances with respect to the position of the GZ* Filter, guidewre-assisted techniques may be

Case 2:15-mC is a Couldering to the intermittence of the stop a guidewire equilding description of the country of the Case 2:15-mC is the stop of the country of the Case of the country o

Each G2* Filter is supplied preloaded in a detivery device. Each G2* Filter system is startle and noncyrogenic unities the peckage is derreged or desired, and is ready for single size only if the Elect is insovationally discharged do not electropic to exhanitize or release.

WARNING: After use, the G_s^{μ} Fitter system and accessorise may be a potential biohaterd. Hendie and dispose of in accordance with accepted medical procise and applicable local, aters and federal laws and regulations. The GP Filter system should be stored in a cool (room (emperature), dark, dry place.

Bard Perspheret Vascular warrants to the first purchaser of this product that this product will be tree from detects in metadata and workmanship for a period of one year from the date of first purchase and tability under tall timited product warranty with be limited to repair or replacement of the defective product. In Bard Peripharat Vascular's cale discretion or refunding your net price paid. Wear and teer from normal use or defects resulting from interes of this product are not

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- Berd Porjheret Vescular to see if additional product information is evidable.

 For additional vens cave life clinical information beare eith to the bilewing societal guidelines:

 "Peactice Guideline for the Performance of Percutaneous Inferior Vens Cave Filter Placement for the Pervention of Pelanonery Embotism" (ACR Practice Guideline 2007; 38:673-864)

 "American College of Cheat Physicians: Opinions regarding the diagnosis and management of venous Informational College of Cheat Physicians (Pelanonery Embots the American College of Cheat Physicians (Cheat 1985 Feb; 113)2; 1498-64]

 "Practice Management Guidelines for the Prevention of Venous Thromboembolism in Trauma Patients; The SAST Perceits Management Guidelines Work Genur 1.1 Trauma 2015-64-648
- Practice Management Suitement (Verk Group* (U Trenna 2002; 55:142-614)

 "Quality Improvement Suitelines for Percutaneous Intellior Vens Cave Päter Placement for the Prevention of Pulmenery Embolism" (JANR 2009; 14:5271-5275)

References:

- Quality improvement Guidahnes for Percutaneous Permanent Inferior Vene Cave Filter Placement for the Provention of Pulmonery Embolism Grassi, Swan, Cardella, 41 at., J Vasc Interv Rediol 2003; 14: 5271-5275.
- faitist Experience in Humans with a New Retrievable (eferior Vena Cava Fider, Arch, M.: Radiology 2002, 225(3), 835-844.
- 833-844.

 Retifievability of the Recovery Vena Cove Filter After Dwest Times Longer than 180 Deys, Blinken, C, et all. J Vasc Interv Retirol 2006, 17(2), 299-302.

 Experience with the Recovery Filter as a Rebisyable Intender Vena Cove Filter. Grande, J., et al. J Vasc Inforv Redet 2005, 19(4), 1986-193.

 Difficult Retireval of a Recovery IVC Filter. Happpiet, K., et al. J Vasc Interv Redet 2004, 15(6), 645-647.

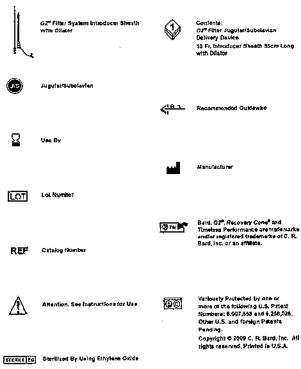
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- n.acco zoxo, 10(9), 1189-1193.

 5. Olificuli Rathavet of a Recovery IVC Filter, Nagspiel, K., et al., J Vasc Interv Radiol 2004, 15(6), 645-647.

 8. Rathavet of Vene Ceve Filter at 224 Cays, Lypman, J.: Southern Modical Journal 2005, 98(5), 559-558.

 Retirent of the Bard Recovery Filter from a Superior Vene Cayor, Rajan, D., et al., J Vasc Interv Radiol 2004, 15(10), 1169-1171.
- Retrovable Interior Yers Cava Filters: Initial Clinical Retoks, Rosenthal, D., et al.: Annals of Vancular Surgery 2008, 20(1), 157-165.



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ENGLISH

Instructions for Use For use in the Vena Cava

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a phytician. A. General Information

The 62* Filter represents a new generation of venous interruption devices designed to prevent pulmonary embolism. The unique design and material of the 62* Filter provide filtering efficiency and allow percutaneous placement through a standard 7 Fernant D. angiographic invoducer catheter with minimum entry site difficulties. The piscement procedure is quick and simple to perform.

This Femoral set is designed to advance through its 48 cm. 7 French I.D. introducer catheter using a flexible, nilinol pusher wire. A pad at the end of the wire is designed to push on the filter spex and a groover segment is designed to hold and properly orient the filter legs. These components secure the titer to line pusher wire as it advances the filter, the first, to the distall and of the catheter, positioned 1 cm below the lowest renal vein. When the tip of the filter approaches the tip of the introducer catheter. ster, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back onto the pusher wire handle to unsheathe and release the filter and allow it to recover to its predetermined shape. The centering system allows the G2® Filter to be deployed with the filter tip centered and minimizes the potential for logs crossing. The G2* Filter is designed to act as a permanent filter. When clinically indicated, the G2* Filter may be percutaneously removed efter implantation according to the instructions provided under the Optional Removal Procedure. The G2^o Fitter's elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is perculaneously removed. (Reference Optional Procedure for Filter Removal for specific removal instructions.)

MRJ Safety:

Non-clinical testing has demonstrated that the G2* Filter is MR Conditional, It can be scanned safety under the following conditions

- Static Magnetic Feld of 1.5-Tesla or less;
- Spatial gradient field of 450 Gaussiam or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of

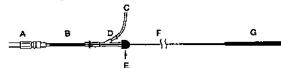
In non-clinical testing, the GZ* Filter produced a temperature rise of tess than or equal to 0.8°C at a maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of MR scanning in a 1.5-festa, General Electric Healthcare MR scanner.

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the G2* Filter Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

The G2® Filter System - Femoral consists of the filter and delivery system. The G2® Filter consists of twelve, shape-memory nilinol virus emanating from a central nilinol eleave. These twelve wires form two levels of filtration of embolic the logs provide the lower level of filtration and the arms provide the upper level of filtration. The G2® Filter is intended to be used in the inferior vena cave (IVC) with a digmeter less than or equal to 28 mm.

The GZP Filter System - Fernoral is illustrated in Figure A. The delivery system consists of a 7 French I.O. introducer carneter and dilator, the GZ* Fitter, a storage tube with saline infusion port, and a

Figure A. G2* Filter System - Femoral



- NTRODUCER CATHETER
 FILTER STORAGE TUBE
 FILENE ORIPINFUSION SET
 SICE PORT
 ADJUSTABLE TOUHY-BORST ADAPTER
- NITINOL PUSHER WIRE PUSHER WIRE HANDLE

IMPORTANT: Read instructions carefully before using the G7 Filter

pusher system. The G2® Filter is packaged pre-loaded within the delivery storage tube.

C. Indications for Use

The G2* Filter System - Femoral Is noticeted for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations

- Pulmonery thromboembolism when anticoagutants are contraindicated
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of convertional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therepy has failed or is contraindi-
- G2* Fitter may be removed according to the instructions supplied under Section labeled: Optional Procedure for Filter Removal.

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

D. Contraindications for Use

The GZ* Fifter should not be implanted in: Pregnant patients when Eucroscopy may endanger the fetus. Risks and benefits should be

- Patients with an IVC diameter larger than 28 mm. Patients with risk of septic emboism

G2⁵ Fitter Implantation

- The G2* Filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the G2* Filter cannot be safely reloaded into the storage tube.
- Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution # 4.)
- Delivery of the G2º Filter through the Introducer catheter is advance only. Retraction of the pusher wire during delivery could result in dislodgment of the filter, crossing of filter ligs or arms, and could prevent the filter from further advancement within the introducer catheter.
- The G2® Filter System Femoral is designed for femoral approaches only. Never use the G2® Filter and Delivery System for superior approaches (jugular, subclavian or antacubital veln), as this will result in improper G2® Filter orientation within the IVC.

 If large thrombus is demonstrated at the initial dolivery site, do not attempt to deliver the
- filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate also. A small thrombus may be bypassed by the guidewire and introducer catheter.
- Only use the Recovery Conse Removal System to remove the GZ® Filter. Never re-deploy removed filter
- Rever advance the guidewise or introducer cathoter/dilator or deploy the filter without fluo-
- Fifter fractures are a known complication of years cave filters. There have been so reports of serious pulmonary and cardiac complications with vens cave filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
- Movement, migration or titl of the filter are known complications of vena cava filters Migration of filters to the heart or furings has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate babled dimensions specified in this IFU. Migration may also be caused by improper deptoyment, deployment into clots and/or disind/gement due to large clot burdens.
- Persons with allergic reactions to nickel may suffer an allergic response to this implant.
- After use, the $G2^8$ Filter System and accessories may be a potential blohazard. Hendle and dispose of in accordance with accepted medical practice and applicable laws and regulations.
- Potential Complications section for further information regarding other known filter complications.

G2* Filter Removal

- Do not attempt to remove the G2º Filter If significant amounts of thrombus are trapped in the filter or if the filter tip is embedded within the vens cave wall NOTE: It is possible that complications such as those described in the "Warnings", "Precautions", or "Potential Complications" sections of this instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the
- device remain permanently implanted.

 Use only the Bard Recovery Cone® Removal System (packaged separately) to retrieve the G2® Filter. Use of other removal devices has resulted in recurrent pulmonary embolism.
- Never re-deploy a removed filter.

F. Precautions

62* Filter Implantation

- This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.
- This device has neither been studied in pregnant women, nor in sur
- Anatomical variances may complicate filter insertion and deployment. Careful attention to these instructions for the can shorten insertion time and reduce the likelihood of difficulties.
- Position the filter tip 1 cm below the lowest renal valit. Venacavography must always be par-formed to confirm proper Implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
- When measuring caval dimensions, consider an angiographic cathater or IntraVasculat Ultrasound (IVUS) if there is any question about caval morphology.
- omassing (trop) shade is an year of all of the filter occurs, consider immediate removal. Do not attempt to reposition the filter. Retieve the 62° Filter using a Recovery Cone® Removal System only. Refer to the Optional Procedure for Filter Removal section for details. Spinal deformations: It is important to exercise care when contemplating implantation in patients
- with significant kychoscolictic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may make percutaneous removal of the filter more
- In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
- If resistance is encountered during a femoral insention procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the vening the vening the contrast medium. thrombus may be bypassed by the guidewire and introducer.
- The introducer catheter has radiopaque markers to assist in visualization and predeptoymen filter positioning. The radiopaque markers on the introducer catheler provide a "target" tocation between which the filter should be positioned just prior to unsheathing and deployment.
- The introducer cetheter hub has a special internal dusign. Care should be taken to make conections firmly, but without excessive force that may cause breekege of the hub.
- It is very important to maintain introducer catheter palently with the saline flush so that the
 ground segment that holds and properly arients the litter legs does not become covered by clot. This will interfere with filter deployment.
- Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unstreather the stationary filter by withdrawing the introducer calleter. Do not twist the pusher wire handle at anytime during this procedure.

G2® Fliter Removal

- Analomical variances may complicate insertion and deployment of the Recovery Cone Removal System Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
- Spinal deformations: It is important to exercise care when contemptating removing the GZ**
 Fitter with the Recovery Conc* Removal System in patients with significant kyphoscolotic spinal deformations because the IVC may follow the general course of such anatomic deformations.
 This may require advanced interventional techniques to remove the filter.
- Remove the 62* Fitter using the Recovery Cone Removal System Only. (Reference Optional Procedure for Fitter Removal for specific removal instructions).
- The cone must be fully retracted into the Y-adapter before connecting the system to the intro-ducer catheter to ensure that the cone can be properly delivered through the catheter

Note: Standards and guidelines developed by the Society of interventional Radiologists recommend that patients with filters (either permanent or retrievable) be tracked and receive "routips follow-up" subsequent to the placement of the device

(1)

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See Reporting Standards for inferior Vera Caval Filter Placement and Patient Follow-up: See Reporting Standards for interior varia Cavas Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters, Millward, S., et al.; J. Vacc Interv Radiol 2005; 16:441-443; Recommended Reporting Standards for Vena Cava Filter Placement and Patient Follow-up. The Participants in the Vena Caval Filter Consensus Conference: J Vesc Inter Radiol 2003; 14:5427-543; Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. Kaufman, J., et al.: J Vasc Interv Radio! 2006; 17:449-459.

G. Potential Complications

Procedures requiring perculaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the omocedure

Possible complications include, but are not limited to, the following:

- Movement, migration or tilt of the litter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reponed. There have also been reports of caudal migra-tion of the filter. Migration may be caused by piscement in IVCs with diameters exceeding the encroenate labeled dimensions specifies in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.
- Filter tractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fregment utilizing endovescular and/or surgical techniques
- Perforation or other acute or chronic damage of the IVC wall.
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage, it is not knows if thrombi passed through the fitter, or originated from superior or collateral vessels
- Deep vein thrombosis
- Caval thrombosis/occlusion
- Extravasation of contrast material at time of venacavogram.
- Hematoma or nerve injury at the puncture site or subsequent reviewal site.
- Hemorrhage
- Restriction of blood flow.
- Occlusion of small vessels
- Distal embolization
- Infection
- Intimal tear
- Stenosis at implant site.
- Failure of filter expansion/incomptete expansion.
- Insertion site thrombosis
- Filter mateosition
- Vessel injury
- Arteriovenous fistula
 Back or abdominal pain
- Filter Tilt
- Hemothorax
- Organ injury
- Phlenmas a carulea dolons
- Pneumothorax
- Postphielatic syndrome
- Stroke
- Thromhophlabitis
- Venous Ulceration
- Slood Loss
- Guidewice entranment

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications, including death, associated with the use of years cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Required

- The following equipment is required for use:
 One G2º filter and Delivory System that contains:
 One 48cm, 7 French I.C. introducer catheter and dilator set
 One 5torage tube with pre-loaded G2º Filter and pusher delivery system
 0.038° 3mm J-bpped Guidewine, 110cm long or longer
- 18 gauge entry needle
- Contrast medium
- Storile extension tube for seline drip or sydinge for saline infusion
- All basic materials for venipuncture: Scalpel, #11 blade, local anesthesia, drepes, etc. the physician chooses to perculaneously remove the GZ^o Filter, the Recovery Cone® Removal System is available from C.R. Bard, Inc.

L. Directions for Use

Insection of the 7 French Introducer Catheler and Prefiminary Venography

- Select a suitable femoral vanous access route, on either the right or left side, depending upon the patient's size or anatomy operator's preference or location of vanous thrombosis.
- Prep, drape and anesthetize the skin puncture site in standard fashion.
- Select and open the filter package. Open Kit A Introducer Catheter package.
- Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
- Insert the J-tipped guidowire and gently advance it into the distal vana cave or iliac vein. Precaution: If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
- Remove the venipuncture needs over the J-Epped guildevilre. Advance the 7 French introducer catheter together with its tapered dilator over the guildevilre and into the distal vena cava or the

Precaution: The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "terget" location between which the filter should be positioned just prior to unaheathing and deployment

Remove the guidewire and dilator, leaving the introducer catheter with its tip in the distal vena cava or itiac vein. Flush intermittently by hand or attach to the introducer catheter a constant seline drip infusion to maintain introducer calheter patency.

Procaution: The introducer catheter hub has a special internal design. Care should be b to make connections firmly, but without excessive force that may cause breakage in the hub.

Perform a standard inforior venecovogram (typically 30 mL of contrast medium at 15 mL/s).

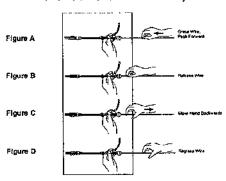
Check for caval thrombi, position of renal voins and congenital anomalies. Select the optimum tevel for filter placement and measure the IVC diameter, correcting for magnification (typically 20

- Advance the introducer catheter to the setected level under fluoroscopic control. The guidawire
 and dilator should be reinserted to facilitate this. For femoral insertion, the introducer catheter to should be 1 cm below the lowest renal vein.
- Remove the litter and delivery system from Kit 8 and flush with saline.

Precaution: It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.

- Attach the free end of the filter storage tube directly to the introducer catheter afready in the vein. The introducer catheter and filter delivery system should be held in a straight line to mini-
- 12. Advance the filter by moving the nitinol pusher wire torward through the introducer cetheter, advancing the filter with each forward motion of the pusher wire (Figures A-D). Do not pull back on the pusher wire, only advance the pusher wire forward. For the operator's convenience, the be looped, without causing kinking to the nitinol material, to fecilitate pusher wire handling and advancement

Advancement of G2* Filter, Illustrated



13. Continue lonward movement of the pusher wire until the filter tip advances to the radiopaque marker on he distal end of the introducer catheter. At this point, the cusher wire handle should be adjacent to the Y-adapter.

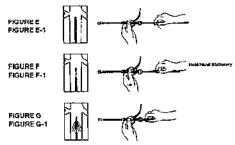
Filter Release/Deployment

14. Deliver and release filter as described below:

Figure E: Firmy hold the pusher wire handle. Keep this hand stationary throughout the entire litter releases degloyment process.

Figure E-1: Fitter positioned in introducer catheter between the radiopaque markers prior to deployment in IVC.

G2® Filter Release, Illustrated



Precaution: Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheathe the stationary filter by withdrawing the introducer catheter as described below. Do not tweet the pusher wire handle at anytime during this procedure.

Position the filter tip 1 cm below the lowest renal vein.

Figure F; With one hand held stationary, the other hand draws the Y-adapter and storage tub assembly back completely over the handle, uncovering and releasing the filter. Ensure that there is no slack or bend in the system during the litter rulease/deployment process. The Y-adapter and storage tube assembly should be retracted in one smooth, continuous motion Figure F-1: Unsheathing of filter in IVC.

Figure Q: The position of the hands at the completion of the unsheathing process Flaure G-1: The filter deployed in the IVC.

- Now withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and introducer catheter assembly and pulling back on the pusher wire. Do not twist the pusher wire handle at anytime during this procedure.
- 16. Resume the intermittent saline flush or constant drip infusion to maintain introducer catheter

Follow-up Vencavogram

- 17. A follow-up venecevogram may be performed after withdrawing the introducer catheter into the itied vein (typically 30mL of contrast medium at 15mL/s).
- Remove the introducer catheler and apply routine compression over the puncture site in the usual way to achieve hemostasia

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

CAUTION: Remove the G2* Filter using the Recovery Cone* only.

Removal of G2* Filter

Equipment Required

The following equipment is required for use:

- One Recovery Cone® Removal System that contains:
- One 75 cm, 10 French I.D. introducer catheter and dilator set -One Y-adapter with Recovery Cone® and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm tong or langer
- 18 gauge entry needle
- 12 French dilator
- Saline
- Contrast medium

(2)

Case 2:15-md-02641-DGC Document 11012-2 Filed 05/07/18 Page 74 of 119

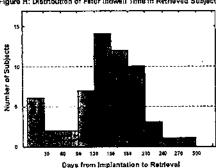
- Starite extension tube for saline dnp or syringe for saline infusion
- All basic materials for venipuncture; scalpel, #11 blade, local anesthesia, drapes, etc.

Clinical Experience

A clinical study involving 100 patients was conducted to assess the safety of removal of the GZ^o Filter. 61 patients underwent a filter retrieval procedure in which 58 had successful retrieval of their Filter. Of the 42 patients that did not have their filter retrieved, 6 died of unrelated causes, 3 withdraw, 2 become lost to follow up and 31 were either not clinically indicated for filter retrieved, 5 with the critical patient could be considered for filter retrieved eligibility criteria during the period in which his patient could be considered for filter retrieved approach (within 6 months after filter placement.) The mean age of the 61 patients who underwent a retrieval procedure was 48 years with a range of 19.3-81.6. The indications for filter placement included DVT anti/or PE with contraindication to anticoagulation, DVT anti/or PE with complication or failure of anticoagulation, and prophylaxis.

The time to retrieval in the 58 patients with successful filter retrievels ranged from 5 to 300 days with a mean of 140 days and median of 144 days. Please see the histogram in Figure H depicting the time

Figure H: Distribution of Filter Indwell Time in Retrieved Subjects



Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Conse Removal System due to filter till leading to embedding of the filter apex into the vane caval wall. One of the 58 successful filter retrievals involved a filter that was reviewed in spike of till and associated embedding of filter apex into caval wall.

There was one symptomatic complication in the study. A patient reported low back pain after a suc-coast, filter placement. On pro-retrieval imaging, two (2) of the filter arms were found to be penetraling the caval wall. The filter was successfully retrieved and the pain resolved.

Asymptometic complications included caudel migration (n=10), fracture (n=1), PE (n=2), filler tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval sterosis at impiant site post successful retrieval (n=1).

Procedural Instructions

Insertion of the Introducer Catheter

- Salect a suitable jugitar venous access route on either the right or left side depending upon the patient's size or analomy, operator's preference, or location of venous thrombosis.
- Prep, drape and anesthetize the skin puncture site in standard fashion
- Select and open the Recovery Cone® Removal System package. Open Kil A Introducer
- Nick the skin with a #11 blade and perform veriguncture with an 18-gauge entry needle.
- the guidewire and gently advance it to the location of the G2° Filter for removal.
- Remove the vanipuncture needle over the guidewire.

 Pre-dilate the accessed yessel with a 12 French dilator.
- Advance the 10 French introducer catheter together with its tapered dilator over the guidawire and into the vein.

NOTE: The introducer catheter has a radiopague marker at the distal end of the catheter sheath to assist in visualization.

- Remove the guidewire and dilator, tearing the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
- Perform a standard inferior venacavogram (typically 30 mt, of contrast medium at 15 mt/s) Chack for thrombus within the filler. If there is significant thrombus within the filter, do not ramove the G2º Filter.

Recovery Cone® Removal System Insertion and Delivery

- Remove the Recovery Cone® Removal System and pusher system from Kit 8.
- 12. Flush the central lumen of the cone catheter and wat the cone with saline—preferably haparin-
- 13. Slowly withdraw the cone into the Y-acepter to collapse the cone and flush with saling PRECAUTION: The cone must be fully retracted into the Y-adapter before connecting the systern to the introducer catheter to ensure that the cone can be properly delivered through the
- Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and filter delivery system should be held in a straight line to minimize fric-
- 15. Advance the cone by moving the pushor shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
- Continue forward movement of the pusher shaft until the cone advances to the radiopaque marker on the distal and of the introducer catheter. Unshaathe to open the cone by stabilizing the pusher shaft and retracting the introducer catheter.

Capture of G2® Filter

G2® Filter Removal, Illustrated

The capture of the G2^o Filter is tlustrated in Figures A-E;

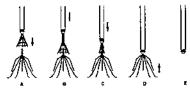


Figure A: After the cone has been opened superior to the filter, advance the cone over the filter up by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-obtique fluoroscopic image to confirm that the cone is over the filter tip

Figure B: Close the cone over the filter tip by advancing the introducer catheter over the cone while holding the pusher shaft stationary.

Figure C: Continue advancing the introducer catheter over the cone until the cone is within the intro-

Figure D: With the cone collegsed over the filter, remove the filter by stabilizing the introducer catheter and retracting the pusher shalf in one, smooth, continuous motion.

Figure E: The filter has been retracted into the catheter.

- 18. Examine the filter to assure that the complete filter has been removed.
- Follow-up Vanacavogram
- 19. A follow-up venacavogram may be performed prior to withdrawing the Introducer catheter (typically 30 mL of contrast medium at 15 mUst.

 Remove the introducer catheter and apply routine compression over the puncture site in the
- usual way to achieve hemostasis.

Guldewire - Assisted Techniqua

Due to anatomical variances with respect to the position of the G2° Filter, guidewire-assisted tedaniques may be used.

Use of a Guidewire

If it is difficult to align the cone with the G2* Filter tip, one may use a guidewire to facilitate advancement of cone over the filter tip.

Withdraw the introducer catheter and cone shaft away from the filter tip. Insert a 0.035" guidawire through the central fumer (J-tipped or angled tip, a hydrophilo-costed guidewire is recommended). Advance the guidewire through the cone and through the filter near the filter tip.

After it has been confirmed that the guidewire is in contact with or in close proximity to the filter tip, advance the cone over the guidewire to the filter tip.

Advance the introducer catheter to slightly collapse the cone over the Filter tip. Withdraw the guidewire into the pusher shaft.

Continue removing the Filter as described in step 17

J. How Supplied

Each G2* Filter is supplied preloaded in a storage tube. Each G2* Filter is sterile and nonpyropenic unless the package is damaged or opened, and is ready for single use only. The storage tube and delivery system are pre-assembled. If the filter is inadvenently discharged, do not altempt to re-

Warning: After use, the GZ* Filter Delivery System and accessories may be a potential biohaz-ard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The G2® Filter should be stored in a cool (room temperature), dry place.

K. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in melenals and workmanship for a period of one year from the date of first purchase and liability under this timited product warranty will be limited to repair or replacement of the defective product, in Bard Paripheral Vascular's sole discretion or refunding your net price paid. Wear and teas from normal use or defects resulting from misuse of this product are not covered by this limited war-

TO THE EXTENT ALLOWARIE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, INIS LIMITED PRODUCT WARROWS IN IN LIEU OF ALL OTHER WARRANTES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

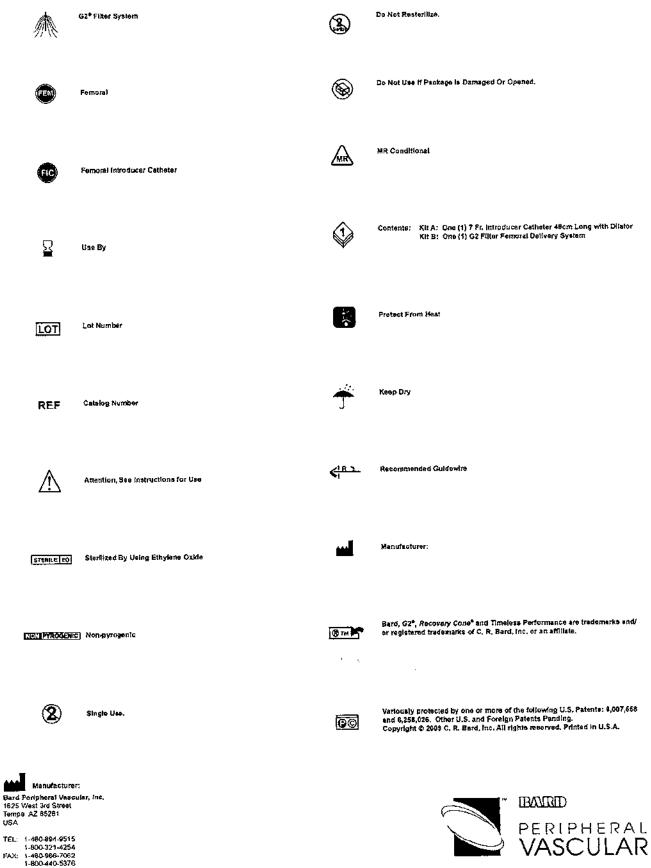
Some states/countries do not allow an exclusion of implied warranties, incidental or consequents damages. You may be entitled to additional remedies under the laws of your state/country. An issue or rowsion date and a revision number for these instructions are included for the user's information on the lest page of this booklet. In the event 38 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.

For additional vens cave filter clinical information please refer to the following societal guidelines:

- "Practice Guideline for the Performance of Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [ACR Practice Guideline 2007; 38:673-684]
- "American College of Chest Physicians: Opinions regarding the diagnosis and management of various thromboembolic disesso. ACCP Consensus Committee on Pulmonary Embolism. American College of Chest Physicians" [Chest 1998 Feb; 113(2); 499-5041
- "Practice Management Guidelines for the Prevention of Venous Thromboembolism in Trauma Patients: The EAST Practice Management Guidelines Work Group" [J Trauma 2002; \$3:142-614]
- lines for Persulaneous Inferior Vens Cava Filter Placement for "Quality Improve the Prevention of Pulmonary Embolism* [JVIR 2003; 14:S271-S275]

- Quality Improvement Guidelines for Percutaneous Fermanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonery Embolism. Grassi, Swan, Cardella, et al.: J Vasc Interv Rediol 2003; 14:S271-S275.
- Initial Experience in Humans with a New Reutevable Inferior Vena Cava Filter, Asch, M.: Radiology 2002, 225(3), 835-844.
- Retrievability of the Recovery Vena Cava Filter efter Owell Times Longer than 180 Days, Binkert, C., et al.: J Vasc Intery Radiol 2006, 17(2), 299-302.
- Experience with the Recovery Filter as a Retrievable Inferior Vena Cava Filter. Grande, J., et el. J Vasc Interv Radiol 2005, 16(9), 1189-1193.
- Difficult Retrieval of a Recovery IVC Filter, Hegspiel, K., et al.: J Vasc Interv Radiol 2004, 15(6),
- oval of Vens Cove Filter at 224 Days, Lipman, J : Southern Medical Journal 2005, 98(5), 6. 556,558 Retrieval of the Bard Recovery Filter from a Superior Vena Cava, Rajan, D., et al.: J Vast Interv
- Rediol 2004, 15(10), 1169-1171. Retrievable Inferior Vena Cava Filters; Initial Clinical Results, Rosenthal, D., of al.: Annals of Vascular Surgery 2006, 20(1), 157-165.

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EXHIBIT DD



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G2 FILTER SYSTEM

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Clot Trapping and Caval Patency

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Secure Fixation

Now featuring a wider legisper and thefeer feature hooks, the newly enthanced G2T features and impleation across an even broadler range of caval distances and higher pressures."

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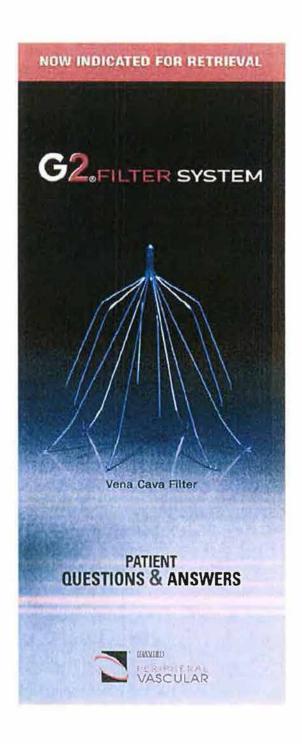
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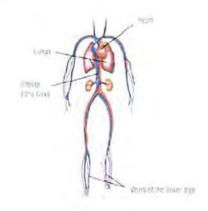
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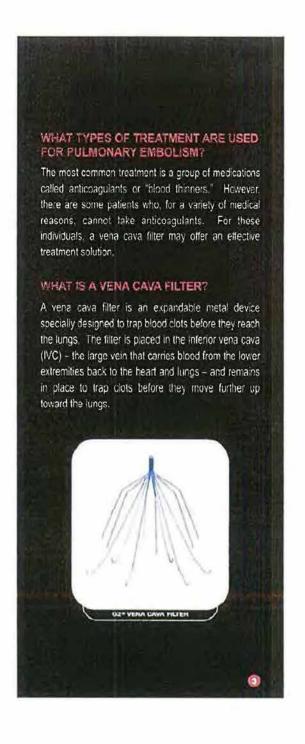
PULMONARY EMBOLISM AND VENA CAVA FILTERS

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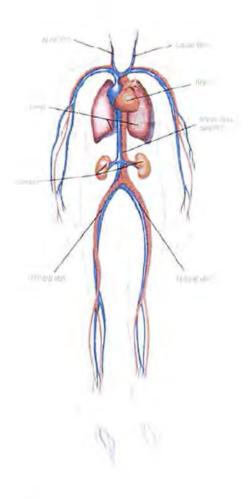
WHAT IS PULMONARY EMBOLISM AND WHAT CAUSES IT?

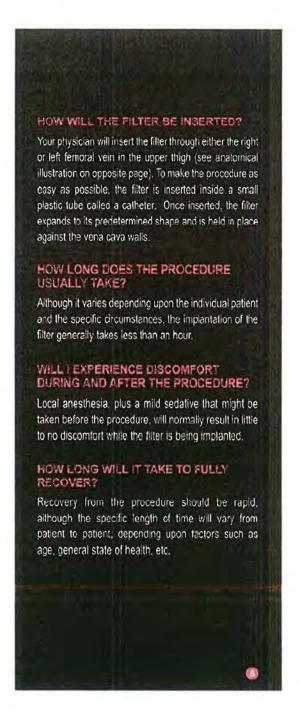
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THE IMPLANT PROCEDURE

The anatomical sites identified below will provide general guidance on those areas that are important in an implant procedure.





AFTER THE PROCEDURE

HOW LONG WILL THE FILTER LAST?

The G2* Fifter is designed to be a permanent implant and will not need to be removed, repositioned, or replaced.

CAN THE FILTER BECOME CLOGGED?

In the great majority of cases, the answer is "no." Once a clot becomes entrapped in the filter, the normal flow of your blood through the vena cava and the filter will usually dissolve a trapped clot as the blood flows over it.

IF I SHOULD NEED AN MRI EXAM, WILL THE METAL FILTER INTERFERE WITH THE TEST?

The G2⁸ Filter is made from an alloy of nickel and titanium, and will not interfere with the test.

UNDER WHAT CIRCUMSTANCES SHOULD I CONTACT THE DOCTOR RIGHT AWAY?

You should contact your physician right away if you experience any of the following:

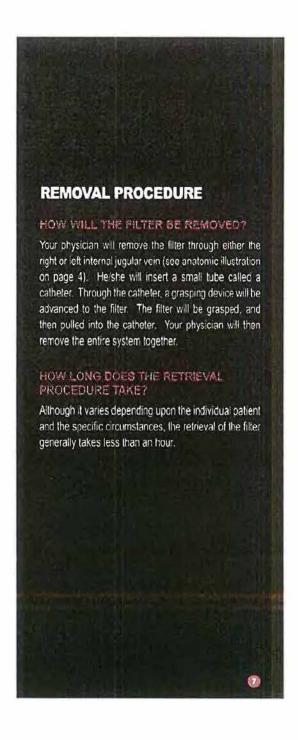
- sudden onset of chest pain accompanied by shortness of breath
- · swelling in both legs
- · unexplained pain in the abdomen

CAN THE FILTER BE REMOVED?

Yes. The filter can be removed when your physician determines that you no longer need it.

WHEN CAN THE FILTER BE REMOVED? IS THERE A "CUTOFF DATE" BY WHICH THE FILTER MUST BE REMOVED?

The G2® Filter does not have a time limit in which it must be removed. The filter can be removed at any time after the point at which you no longer need it. This is up to your physician.



WILL I EXPERIENCE DISCOMFORT DURING AND AFTER THE PROCEDURE?

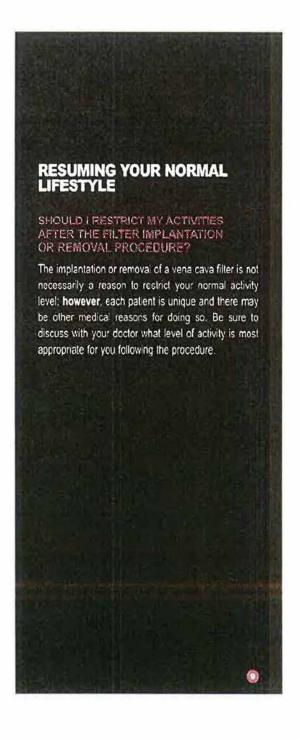
As with the implant procedure, local anesthesia, helped by a mild sedative given before the procedure, will normally result in little to no discomfort while the filter is being removed. Afterwards, you may experience mild soreness in your neck for a few days. This is normal and will disappear. You will be left with a small scar on your neck at the puncture site.

HOW LONG WILL IT TAKE TO FULLY RECOVER FROM THE REMOVAL PROCEDURE?

Recovery from the removal procedure should be rapid, although the specific length of time will vary from patient to patient, depending upon factors such as age, general state of health, etc. Typically, you will be discharged several (2-3) hours after the procedure.

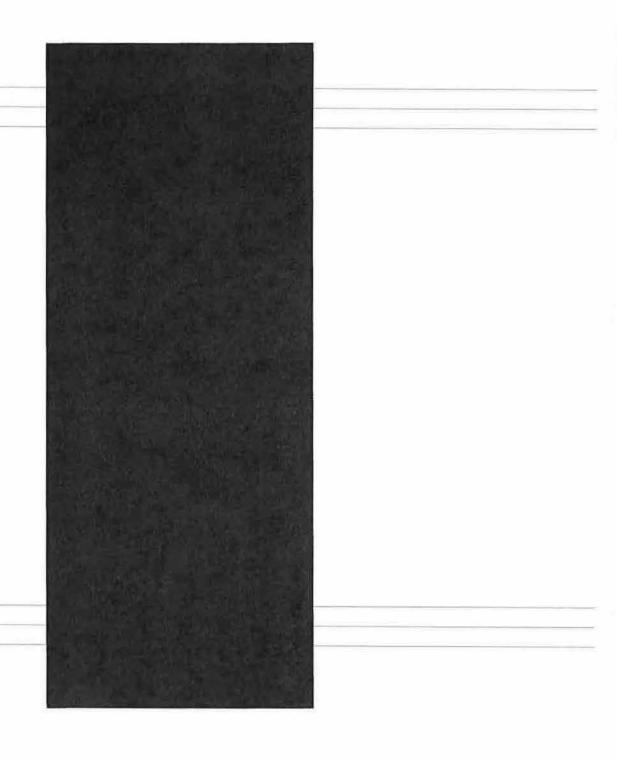
DOES THE FILTER HAVE TO BE REMOVED?

No. The G2* Filter is designed to be a permanent implant and does not have to be removed, repositioned, or replaced.

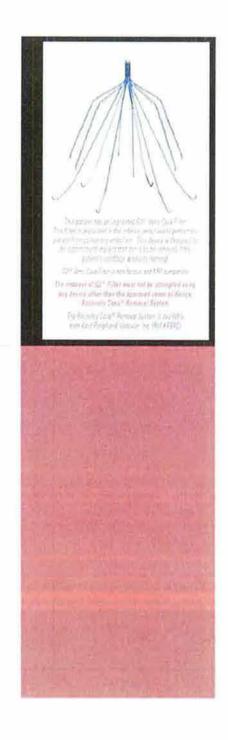


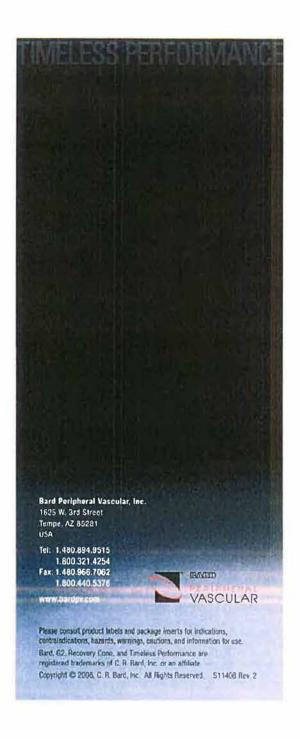
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G2® Filter System Jugular/Subclavlan Vein Approach Instructions for Use



ENGLISH

Instructions for Use

For use in the Vena Cava

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A General Information

The Q2* Filler represents a new generation of venous interruption devices designed to prevent purmonary embo-ism. The unique design and material of the Q2* Filler provide friering efficiency and allow percubaneous placement through an angiographic Mitroducar with manimum entry sits difficulties. The placement procedure to quick and

strating an engage on strategy when the content of the content of

procuraneously services. Attentions depoints independent or stats removal the specimic minorial networks. Non-diminish feating has demonstrated that the GP[#] Fitter is AR Conditional. It can be sconned safely under the following conditions:

1. British Magnette field of 1,5-Teals or less;

2. Spatial gradient field of 45 Causalem or less;

3. Maximum whole-body-everaged specific absorption rate (SAR) of 1,5 W/lig for 20 minutes of economic.

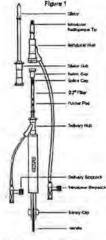
nan-clinical testing, the G2* Fitter produced a lamperature rise of less than or equal to 0.6°C et a maximum which everaged specific elsection (eta (SAR) of 1.5 Wiley for 20 minutes of MR scanning in a 1.5-Tasta, General Electric Heathcare MR scanner.

MR image quelty may be complemed if the area of interest is in the exect same area of reletively close to the position of the QZ^a Filter. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implicit.

B. Device Description

The G2[®] Fight- Jugular/Subclavian System consists of the filter and delivery system. The G2[®] Filter can be delivered Via the femoral and jugular/subclavian approaches. A separate cellvery system is evaliable for each approach. or consists of twelve shape-namery milited wires amenaling from a contral nation sterve. These twelve to levels of filtration of embos, the lega provide the tweer level of filtration and the arms provide the upper level of filtration.

The G2* Filter System Jugular/Subctavion is streamed in Figure 1. The Delivery System consists of a 10 French 1.0. microducer sheath and distor, the G2* Filter is packaged pro-leaded within



IMPORTANT: Read treductions carefully before using the GZ* Files

C. Indications for Use

The Q2* Filter System-Jugular/Subclavien is indicated for use in the prevention of recurrent putmonary embatism via permanent placement in the vene cave in the following ellustries:

- Putmonery thromeoembofem when anticosplustries are contentiated.

- Faiture of anticosplustriempy for thromeombof classes.

- Emergency theiriment following measure putmonary embodism where smitosplated benefits of conventional Biarrayy are reduced.

- Chreate, recurrent pulmonary embodism where embodism where smitosplated benefits of conventional Biarrayy.

- 22* Filter may be removed apporting to the instructions supplied under Bedion labeled: Optional Procedure for Filter Removel.

- Contraint features for these. The OZ Fitter System-Jugular/Subclavian is indicated for use in the prevention of recurrent pulmonary ambatism vis

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

- The GP Filer should not be implanted in:

 Proposed patients when Suproceopy may sedanger the folios. Rists and besetts should be essessed carefully.

 Fatients with an IVC dismeter larger than 25 mm.
- Patients with risk of septic embalism.

G2º Fifter Implantation

- * Finer impantation

 The 0.2° Fixe is pre-loaded and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the 0.2° Filter cannot be safely reloaded.

 Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution # 4). It large from the literation of the close of the close
- Never advance the guidewire or introducer sheathightur or deploy the filter without fluoroecopic guid-
- ance.

 Filter fractures are a known complication of vone cave filters. There have been some imports of serious pulmonery and cardiac complications with vene cave filters requiring the retrieval of the inagment utilization and/or surgical techniques.

 7. Movement, migration or the of the filter are known complications of vene cave filters. Migration of filters to the heart or fungs has been reported. These have also been exported exceeding the appropriate backed dimensions specified in this FU. Migration may also be caused by improper deployment, deployment into clots and/or disologement due to large clot burdens.

 Never use the fugular or subclaving delivery system for femoral approach, as this will result in known or 3° Filter orientation within the UVC.

 Whose infection contract medium through the distor, so not exceed the maximum pressure rating of 800.
- When injecting contract medium through the dilator, do not exceed the maximum pressure rating of 800

Case 2:15-md-0264 lunguages to nice Octob Month and Octob Month and Object of 119 11. Affect line, the 0.2° Filter system and access socials may be a potential block and disposs of in accordance with accepted modical practice and applicable local, siets and tenderal laws and regula.

Reference Potential Complications section for further information regarding other known filter complica-

- 10. Do not attempt to remove the G2* Filter if significant amounts of thrombus are trapped within the filter of it the filter tip is embedded within the vens cavel well.
 NOTE: It is possible that complications such as those described in the "Warninge", "Precuritions", or "Potential Complications" sections of the instructions for Use may affect the recoverability of the device and result in the clinician's decision is have the device remain permanently implanted.
- Use only the Bard Recovery Cone® Removal System (packaged asparately) to review the G2® Filter. Use of other removal devices has resulted in recurrent putnocary embolism.
- 3. Never re-deploy a removed filter.

GZ Fiker (mplentation

- This product is intended for use by physicians trained and expenented in diagnostic and interventional tech-
- This device has neither been studied in pregnant women, nor in suprara
- Anatomical valences are completed files beginned and deployment. Careful attention to these instructions for Use can shorten insection time and reduce the likelihood of difficulties. Partition this files that the complete shorten and the shorten and the complete shorten and the shorten
- When measuring coval dimensions, consider an angiographic satisfier or intra/viscolar Udrasound (VUS) if there is any question about caval interplacing. If misplecement, sub-optimal piccoment, or litting of the filter occurs, consider intradular amoval. Do not accord to reposition as little. Reference to 27 Filter using the Recovery Conet Removal System Only. Refer
- to Cyclonal Procedurs for Filter Removal for dribbs.

 Spinal determations: it is important to extends one when contemplating implantation in patients with significant syphecolotics spinal determations because with YOV may follow the general course of such another deformations. This may make percotaneous removal of the filter more difficult.
- In partents with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to enti-
- thrombotic therapy as each as it is deemed safe.
 If resistance is encountered during the insertion p treablance is encountered during the interrior procedure, will draw the guidewire and check vein palancy fluo-reacopically with a small rejection of contract medium. If a large thiorabus is present, remove the venigunchure media and use the value on the opposite side. A small thorothics may be bypassed by the guidewice and lafo-
- 10. Ensure that the introducer and the delivery device hubs are anapped ingeller and that the system has been positioned to aplical piccement, before deploying the Q2* little.

 11. Do not remove the self-by city until the introducer and the delivery device hubs are shapped logether.
- 12 Do not deliver the filter by pushing on the handle, rether retind the introducer hub to properly deploy the 62*
- I it is very important to maintain introduces patency with a sable iteral to prevent occusion of the introduces, which may interface with delivery device advancement.

 4. Applicating the introduces should white leaving the guidewing in place may lead to the introduction of air into the

GZ Filler Removal

- Anabrecal variances may complicate insertion and deployment of the Recovery Conse Removal System.

 Careful attantion to these instructions for Use can shorten insertion time one reduce the likeShood of difficulties.

 Spired deformations: It is important to execute other when confermining removing the OZP Pritar with the Recovery Conser Removal System in pollation with significant typhosocidis graph deformations because the IVO may Nation the general course of such anatomic deformations. This may require advanced interventional interventional course to consider the course of such anatomic deformations. Inchniques to remove the filter.

I secrifiques to remote the Mar.

3. Remove the GP Filter using the Recovery Cone® Removal System Only. Reter to the Optional Procedure for Pitter Removal section to details.

4. The cone must be fully refrected into the Y-adapter before connecting the system to the introducer cathelier to ensure that the one can be properly defined through the cathelier.

Note: Standards and guidelines developed by the Society of interventional Radiologists recommend that patients with riters (either permanent or retrievable) be tracked and positive "routine follow-up" subsequent to the placement of the device.

See Reporting Standards for fine for Vene Cavel Filter Placement and Pettent Follow-up: Supplement or Temporary and Rott-viable/Optional Filters. Matiward, S., et al.: J. Vene Interv. Radiol 2008; 16:441-443; Recommended Reporting Standards for Vene Cavel Filter Placement and Patient Follow-up. The Participants in the Vene Cavel Filter Placement and Patient Follow-up. The Participants in the Vene Cavel Filter Recommended Reporting Standards for Vene Cavel Filter Placement and Patient Follow-up. The Participants in the Vene Cavel Filter Consenies Conference: J Vene Cavel Filter Report from the Society of Inderventional Patient Follow-up. The Participants and Patient Follow-up the Conference of Vene Cavel Filter Report from the Society of Inderventional Patients (Conference Cavel Filter Report from the Society of Inderventional Patients (Conference Cavel Filter Report from the Society of Inderventional Patients (Conference Cavel Filter Report from the Society of Inderventional Patients (Conference Cavel Filter Report from the Society of Inderventional Patients) and Conference Cavel Filter Report from the Society of Inderventional Patients (Conference Cavel Filter Report from the Society of Inderventional Patients (Conference Cavel Filter Patients (Conference Cavel Filter Conseniers Conference Cavel Filter Report from the Society of Inderventional Patients (Conference Cavel Filter Conseniers Conference Cavel Filter Consen The Use of Rainsvable and Convertible Vens Cave Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. Reutman, J., et al.: J Vesc Interv Radiol 2005; 17:449 450.

- O. Potential Complications
 On the possible of complications interventional techniques should not be atempted by physicians unfamiliar way, the possible complications (Complications may occur at any time during or eiter the procedure.)
 Possible complications (include, but are not limited to, the following:
 Movement, mysistor at the other fiet are known complications at venie cave filters. Attigration of filters to the heart or lungs has been reported. Their bises also been reported of excided imprebor of the filter. Malgration may also be caves for lungs are possible to the complication may also be caves to be interest or complication. If U. Wiggisten may also be caves to be improper deployment, deployment is to date another diddogeneral dies to large ofto buttern. lama dor burdens.
- large one outdans.

 Filter hardures are a known complication of vans cave filters. There have been some reports of serious pulmonary and condisc complications with vano cave litters requiring the natrievel of the Regmont utilizing endovescoler and/or surgical technique.

 Performion or other acute or channel damage of the IVC well.

 Apute or required pulmonary embolism. The has been reported despite filter usage. It is not known if prombil peesed through the filter, or originated from superior or sollarism vosads.

- Extravasation of contrast material at time of vanacavogram.
- Hamatoma or nerve injury at the puncture site or subsequent minevet site.
- Hemerchage:
- Restriction of blood flow
- Occionion of small vessels
- Ontal embalization

- Stancais at Implant sie
- Fallule of filter expansion/incomplete expunsion
- Inserton elle thrombosis Fitter maloosition
- Back or abdominal pain
- Organ kilury
- Palegmania cerules dolens
- Postablebilio syndroms
- Stroks Thrombaphiebilis
- Vanous Ulcaration
- Gulgewire entrapment

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All of the shows complications have been associated with serious acverse events autor as medicis interversion and/or seath, There have been reports of complications including death, associated with the use of vens cava filters in morbibly obese patients. The risk/benefit ratio of any of these complications should be weighted against the inherent risk/benefit ratio for a patient who is at tisk of pulmonary embolism without intervention.

H. Equipment Required

- One G2⁶ Fitter Jugular/Subidavlan System that contains:
 -One 65 cm, 10 Franch I.D. Introducer and dilator set
- -One delivery device with pre-loaded G2º Filter 0.030° I rrvn 1-usped Guidewre. 119 cm long or longer
- 15G erkry needle
- Commet medium
- Sterile extension tube for selling drip or syrings for sellins infusion.
 All basic metarials for vanipuncture: scappe; \$11 blade, local ensisteesia, drapes, etc.

If the physician chooses to percutaneously remove the 65° Filter, the Recovery Cone® Removal System is available

L'Directions for Use

- 1. Belect a suitable jugular or subclavion venous eccess route, on either the right or left side, depending upon the pallent's size/anatomy, operator's preference, or location of venous intermibese. Prep, drope, ar d'ansatinatize the skin puncture site in standard testion. Select and open the jugitariavabledrean delivery system package. Tition the skin with a \$11 titles and perform venloprocture with an 150 entry needle.

• Truck the skin with a 511 blace and perform venloperture with an 150 entry needle.
• Intent a J-lipped guidewise and gently edvence 1 into the inferior vane cave.
• PRECAUTION: It resistance is associationed during the issestion procedure, withdraw the guidewise and check vota partency fluoroscopically with a entail injection of contrast medium. If a large thrombus is present, remove the veniplundruse needle and try the velo por the opposite side. A small thrombus may be bypassed by the guidewise and introducer.

Remove the 19Q anily needs over the J-Upped guidewire. Obtain the dilator and the introducer sheath from the package. Flush the dilator and the introducer with seine, losen the dilator through the introducer sheath ensuring that the trube scap together. Anvence the 10 French introducer sheath together with its topered diletor. over the guidewire and into the interior vens cave.

NOTE: A 0.038" guidewire is used to guide the dilefor/introducer assembly bayand the implant all to ensure

proper setvancement.

PRECAUTION: It is very important to maintain introducer petancy with a saline flush to prevent occlusion of

The introductor, which may interfere with delivery device advancement.

2. Partorn a stendard interior venacoupron (typically 30 rd. of contrast roadium at 16mily) through the elitate.

Check for cavel thrombit, position of Frenth vena. and congestal accomplies. Balact the optimizer fever for placement and research the IVC demosts; correcting for requiritieston (typicatry 20 percent).

placement and research the IVG demeter, accrosing the resumment (year of the maximum pressure rating WARNING: When injecting societies medium tarough the cliator, do not exceed the maximum pressure rating

0 500 psi.

WASHAND: If the vans cave diameter is greater than 28mm, do not deploy the G2* Fillar. If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot undor filter may occur. Select an element at his localizer the filter. A small thrombus could be bypeased by the guidewire

Separate the dilator and introducer hubs by bending and then pulling sport (Reference Figure 2). Remove the guidewire and dilator, leaving the 10 Franch introducer sheeth with its tip in the interior varie cave. Flush intermittently by hand or attach to the introducer stopcock a constant salles drip influsion to maintain introducer. patency.

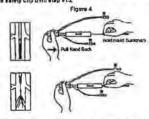


9. Remove the delivery device from the package and remove the red salety cap (Reference Figure 3).



10. Flush the delivery device with splins through the delivery stopcock.

10. Float the delivery device with salins strongs the convery exposor.
11. Insect and advance the Edwary divide introduction the title introducer and delivery device habit energy together (Reference Figure 4).
PRECENTION: Ensure that the introducer and the delivery device habit are enapped together and that the system has been positioned for optimal placament, before deploying the GP* store.
NOTE: Do not remove the safety clip until stop £13.



12. Under Avorascopic control, position the system for optimal placement. The distallend of the pusher ped provides the radiopaque Indicator for positioning purposes (Relationae Figure 5). NOTE: Do not remove the eatinty offe until step \$13.

de.



NOTE: A gap between the filter spee and pusher pad is normal.

12. Remove the selety old from the delivery desi

Otabilize the hereile and put back on the Introducer hab (blue) to retrect both the introducer sheath and deliv-ary device. Retract like introducer hab until the handle bottoms out against the proximal edge of the delivery cathotise hab (white). This will release the G2* filter into position (Reference Figure 8).

PRECAUTION: Do not deliver the filter by pushing on the handle, rather retrect the introducer hub to prop-



Distal End of Pusher Pad

- Separate the delivery and introducer hole by bancing and then pulling apart. Retract and remove the delivery device from the introduced cheets.

 2. Perform a venezarroyzars to confirm settletarry deployment before terminating the procedure.
- Remove the introducer sheath and apply routine compression over the puncture sets is the usual manner to achieve harrowitable.

(3)

CAUTION: Remove the GT⁶ Filter using the Recovery Cone® Removal System only.

Removal of G2ª Filter

- Removal of Q2º Elikar

 Boulphant Required

 The following squipment is required for use.

 One Recovery Cone® Removal System that contains:

 —One 7-5 on, 19 Finesh I.D. Bluckbern eatheler and dilater set

 —One Y-adapter with Becovery Cone® and guaher delivery system.

 10.035° 3 mm J-lipped Guidevire, 110 cm long or longer.

 16 gauge actry needle.

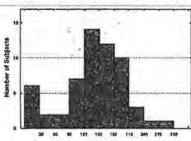
 12 Finnch design.

- Starte extension tube for some dide or syrings for saline infusion.

 All basic materials for versiouncture; scalps, #11 blade, local sessionsis, frepos, etc.

Clinical Experience. A clinical study involving 100 patients was canducted to easess the salety of removal of the G2[®] Filter, 81 patients underwent a filter retrieval procedure in which 58 had successful retrieval of their filter retrieval of selection in the filter retrieval of selection in the filter retrieval of selection in the selection of selection in the filter retrieval of selection retrieval or failed to mean attack and selection for selection for selection or failed to mean selection for selection for selection in the selection for selection for filter pisceromal included DVT and/or PE with control dication in entire or selection. DVT and/or PE with complication for filter pisceromal included DVT and/or PE with control dication in entire selection. DVT and/or PE with complication or selection in the selection in the Selection selection in the selection in the Selection selection in the selection in the Selection selection in Figure 7 depictions that the selection is selected in the selection in the

Figure 7: Distribution of Filter Indwell Time in Retrieved Subjects



Days from Implantation to Retrieval

Of the dil attempted filed rearlevals, 3 fechinel elitures for retrieval resulted from inability to engage the files apoc with the Recovery Coner Removal System due to files this tead git owner between covering of the repex hid cover were covered as files and potentially an experience of the sepax hid cover were covered as filter that was retrieved in spire of till and especially embedding of the five spex hid cover were covered as filter than the service of the sepax hid cover were filter than the service of the sepax hid cover was in the study. A partier reported low back goth after a successibilities plant reached. Asymptomatic complication included caudal migration (n=10), section (n=1), PE (n=2), first tis (n=15), penetration (n=17), care cookalar (n=1), no-occlusive caval thrembods (a=1), and cavel stempts of explaint site post successful referred (n=1).

Proceedizal Instruction;
Insertice of the labeducer Catheter insertion of the labeducer Catheter (n=1).

Proc. the substitute in the second control of the secon Of the 61 attempted filer retrievels, 3 technical itsitures for retrieval resulted from inability to engage the filter spect

- Remove the guidewire and distor, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or extech to the catheter a constant satisf only interior to maintain stroducer catheter pat-

- energy of near or each of the Carriers is consumed as consumer as consumer as consumers or resistant attractable attractions of the Carriers o

Capture of G2º Filter

Filter Removal, Illustrated 17. The capture of the G2* Fittor is slustrated in Figures A-E:

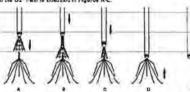


Figure A: After the core has been opened superior to the filter, edversor the zone ever the filter lip by holding the introducer catheter stellonery and advancing be pusher shaft. It is recommended to obtain an antanocobilique sucreacopic image to confirm that the cone is over the filter by being confirmed to obtain an antanocobilique sucreacopic image to confirm that the cone is over the filter by solvening the introducer catheter over the cone write holding the pusher shaft satisfiers.

Figure D: Otherwise advancing the introducer catheter over the cone until the cone is within the introducer catheter.

Figure D: With the cone collepted over the lifter, remove the filter by stabilizing the introducer catheter and retracting the pusher shaft in one, embotin, constructor motion.

Figure D: The filter to greate the complete filter has been removed.

F980w49 Venacevogram
19 A follow-up venacevogram may be performed prior to withdrawing the introducer calindar (typically 31 ref. of non-fresh modern at 15 mUs).
20 Remove the introducer celleter and apply routine compression over the puncture also in the usual way to

achieve hemostasis

Guldewire - Assisted Technique

Due to analomical variances with respect to the position of the G2* Filter, guidawire assisted techniques may be

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It is a difficult to align the cone with the 62* Filer tip, a guid entire could be used to facilitate advancement of corne over the filler tip, Withdraw the introduced coinseler and corne shaft away from the filter tip, finant a 0.035* guidewire through the second corne included by; a hydrophic-coarsing diplewire to recurrenteed. Advanced the guidewire through the second corne included by the filter tip.

Advanced the Introduced continues on the filter tip.

Advanced the Introduced continues one over the guidewire to the filter tip.

Withdraw the guidewire into the pusher shaft, Continues enterwing the Pfilter as described in slep 17.

J. How Supplied

a. now opposes.

Each G2* Filter is supplied perioaded in a delivery device. Each G2* Filter system is starte and noncyrogenic unless the package is garraged or opened, and is ready for single use only. If the filter is inedvertently discharged, we not stample for estating in results in a stample for estating in several in the WAXINNOC After use; the G2* Filter system and accessories may be a potential blohaterd. Handle and dispose of in accordance with accepted medical execution and applicable local, state and federal laws and regulations.

The G7⁶ Filter system should be stored in a cool (room temperature), dark, dry place

her perfectively decided warrants to the first purchaser of this product that this product will be first from delects to materials and workmanship far a period of one year from the date of first perchase and tability under this illmited product yearney will be limited useful or replacement of the delective product, in Bard Perphanik Vescular's sole discribion are related by our replacement of the delective product, in Bard Perphanik Vescular's sole discribion are related by our replacement of the product are not covered by this limited warranty.

TO THE EXTENT ALLOWAGE BY APPLICABLE LAW, THIS UNITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERHERAL VASCULAR BE LIABLE TO YOU FOR ANY IMPRIECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES REBULTING FROM YOUR HANDLING OR USE OF THIS PROBUCT.

Resource that Protein and a constraint on the Country of the Protein and Country of the Country

- For additional vene cave After clinical Information please refer to the following excited guidelines:

 "Practice obligation for the Performance of Parcutaneous Inford Vena Cave Filter Placement for the
 Preveation of Pulmoseus Embotism" (ACR Practice Guideline 2007: 35:873-664)

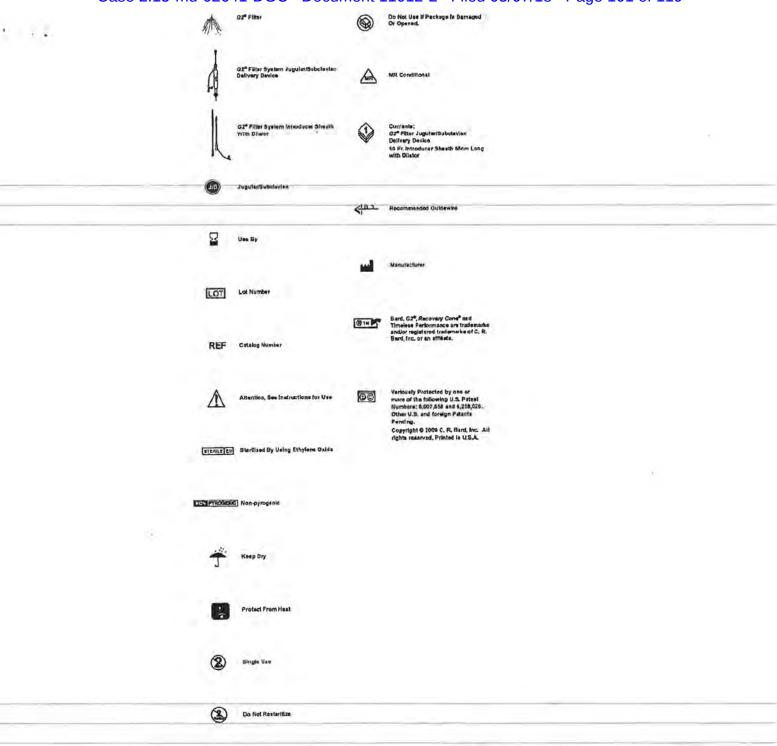
 "Amelican College of Chest Physicians: Opinions regarding the disgnoste and management of venicus
 thrombosmbolic classes. ACCP Consensus Committee on Pulmonery Embotism. American College of Chest
 Physicians" (Chest 1996 Fab; 173/2): 498-504)

 "Practice Management Guidelines for the Perevition of Venous Thrombosmbolism in Tsauma Patients: The
 EAST Practice Management Guidelines for the Prevention of Venous Thrombosmbolism in Tsauma Patients: The
 Cavilly Improvement Guidelines for Percutaneous interior Venous Fitter Placement for the Prevention of
 Pulmonary Embolism" (JVIR 2003; 14:3271-3273)

- Questy Improvement Guidelines for Percusanaous Permanent Elener Vens Cave Filter Procement for the Prevention of Polmonary Embolism. Graset, Swan, Cardefa, et al.: J Vesc Interv Radiol 2009; 14:5271–5275.
- Initial Experience in Humana with a New Retrievable Inferior Vene Cava Fatar. Aach, M.: Radiology 2002, 225(3).
- Reińwstińcy of the Recovery Vene Gave Filter After Dwell Times Longer than 160 Deys. Binken, G., et al.; J Vesc Inter Redoi 2006, 17(2), 209-302.
 Exparience with the Recovery Filter as a Retrevoble Interior Vene Cave Filter, Grands, J., et al.; J Vesc Intervació 2005, 10(9), 1109-1109.
 Dimour Retrival of a Recovery Filter Happhil, K., et al.; J Vesc Interv Redoi 2004, 15(6), 645-547.
 Recovery of Vene Cave Filter 4224 Days. Lloman, J.; Southern Medical Jovinal 2006, 93(5), 556-558.
 Rectovery of the Bard Recovery Filter from a Superior Vene Cave, Rajen, D., et al.; J Vesc Interv Redoil 2004, 15(6), 1169-1171.
 Retrevola infanto Vene Cave Filter 1001.

- Rotevable Interior York Cave Fitent: Initial Clinical Results. Resenting, D., et al.: Annets of Vescular Surgery 2000, 20(1), 157-165.

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TEL: 1-480-894-9515 1-809-321-4254 FAX: 1-480-968-7052 1-800-440-5376 www.berdpv.com



PK5280600 Rev. 1 07/09



ENGLISH

Instructions for Use For use in the Vena Cava

Caution: Federal (U.S.A.) law matrices this device to sale by or on the order of a physician.

The G2* Filter represents a new generation of venous interruption devices designed to prevent pul-monary embolism. The unique design and material of the G2* Filter provide filtering efficiency and allow perculaneous placement through a sienderd 7 French I.O. anglographic introducer catheter with im entry sits difficulties. The placement procedure is quick and simple to perform

The Femoral set is designed to advance through its 48 cm, 7 Franch I.D. Introducer catheter using a flaxible, nitinol pusher wire. A pad at the end of the wire is designed to push on the fiter agex and a grooved segment is designed helid and properly orient the filter legs. These compenents secure the filter to the pusher wire as it advances the filter, to first, to the distell end of the catheter, positioned it cm below the lowest rand vein. When the lip of the filter approaches the 6p of the introducer cathelse, it will be positioned between the radiopsque markers on the introducer cathleter. The introducer cathleter and delivery sessmbly are then pulled back onto the pusher wire handle to unsheathe and roloses the filter and allow it to rocover to its predetermined shape. The centering system allows the GZ* Filter to be deployed with the filter tip centered and minimizes the potential for logs crossing. The GZ* Filter is designed to act as a permanent filter. When clinically indicated, the GZ* Filter

may be percutaneously removed after implantation according to the instructions provided under the Ontional Removal Procedure. The G2® Filter's stastic books allow the filter to remain rigid and restat migration, but stastically deform when the filter is percutaneously removed. (Reference Optional rocedure for Filter Removal for specific removal Instructions.)

Non-clinical testing has demonstrated that the G2* Filter is MR Conditional, II can be scanned safely

- Static Magnetic field of 1.5-Teyla or less:
- Spallel gradient field of 450 Gaussicm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 1,5 W/kg for 20 minutes of

In non-clinical testing, the GZ* Filter produced a temperature rise of less than or equal to 0.8°C at a maximum whole body averaged specific absorption rate (SAR) of 1,5 W/kg for 20 minutes of MR acanning in a 1,5-Testa, General Electric Healthcare MR acanner.

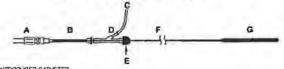
MR Image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the GZ* Filter Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

B. Device Description

The G2º Filler System - Femoral consists of the filter and delivery system. The G2º Filter consists of thelive, shape-memory nilinol wires emenating from a central nilinol afseve. These twelve wires form two levels of filtration of embolt: the logs provide the lower level of filtration and the arms provide the upper level of filtration. The G2* Filter is intended to be used in the inferior vene cave (IVC) with a diameter less than or equal to 28 mm.

The GI^{\bullet} Filler System - Femoral is illustrated in Figure A. The delivery system consists of a 7 French 1.D. introducer catheter and dilator, the GI^{\bullet} Filter, a storage tube with saline intusion port, and a

Figure A. G2ª Filter System - Femoral



- INTRODUCER GATHETER FILTER STORAGE TUBE SALINE DRIP INFUSION SET
- SIDE PORT ADJUSTABLE TOUHY-BORST ADAPTER
- NITINGL PUSHER WIRE PUSHER WIRE HANDLE

IMPORTANT: Read Instructions carefully before using the G?" Filler

pusher system. The G2º Filler is packaged pre-loaded within the delivery storage tube C. Indications for Use

The G2* Filter System - Famoral is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vens cava in the follo

- Pulmonary thromboombolism when enticoagulars are contraindicated
- Failure of anticoegulant therapy for thromboembolic disease.

 Emergency treatment following massive pulmonary embolism where anticipated benefits of convantional therapy are reduced.
- Chronic, recurrent pulmonery embolism where anticoagulant therapy has failed or is contraind-
- G2º Filter may be removed according to the instructions supplied under Section labeled: Optional Procedure for Filter Removal.

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

D. Contraindications for Use

The GZ Fifter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.

 Patents with an IVC diameter larger than 28 mm.
- Patients with risk of septic embolism.

E. Wamings

G2º Füter Implantation

- The GZ^0 Filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the GZ^0 Filter cannot be safely reloaded into the alonge tube.
- Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution # 4.)
- Delivery of the GZ⁰ Filter through the introducer catheter is advance only. Retraction of the pusher wire during delivery could result in dislodgment of the filter, crossing of filter legs or arms, and could prevent the filter from further advancement within the introducer
- The G2* Filter System Ferroral is designed for femoral approaches only. Never use the G2* Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vale), as this will result in improper G2* Filter oriontation within the IVC. If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter brough it as inigration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus way be bypassed by the guidewire and introducer called the second of the clot and or filter may occur.
- Only use the Recovery Com^a Removel System to remove the 62⁵ Filter. Never re-deploy a removed filter.
- Never advance the guidewire or introducer cathemydilator or deploy the filter without fluoroscopic guidance.
- Filter fractures are a known complication of vena cays filters. There have been some reports of serious pulmonary and cardiac complications with vena cays filters requiring the retrieval of the fragment utilizing endovascular and/or surgical lechniques.
- Movement, infigration or its of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.
- Persons with allergic reactions to nickel may suffer an allergic response to this implant.
- After use, the G_a^{eq} Filtor System and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.

Polential Complications section for further information regarding other known filter complications

GZ[®] Filler Removal

- Do not attempt to remove the GZ^o Filter If significant amounts of thrombus are trapped within the filter or if the filter tip is embedded within the vens cave w NOTE: It is possible that complications such as those described in the "Warnings", Prezautions", or "Potential Complications" sections of this instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted.
- Use only the Bard Recovery Cone® Removal System (packaged separately) to retrieve the GZ® Filter. Use of other removal devices has resulted in recurrent pulmonary embolism.
- Never re-deploy a removed filter.

F. Precautions

GZ® Filter implantation

- This product is intended for use by physicians instead and experienced in diagnostic and interventional techniques.
- This device has neither been studied in pregnant women, nor in suprerenel placement position. Anatomical variances may complicate filter insertion and deployment. Careful ettention to these instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
- Position the filter tip 1 cm below the lowest ronal vain. Venacavography must always be per-formed to confirm proper implient site. Radiographs without contrast, which do not clearly show
- the wall of the IVC, may be mislanding.

 When measuring cavel dimensions, consider an angiographic catheter or intraVascular
- Ultrasound (IVUS) if there is any question about caval morphology.

 If misplacement, sub-optimal placement, or litting of the filter occurs, consider immediate removal. Do not attempt to resposition the filter. Relieve the GZ* Filter using a Recovery Cone® Removal System only. Rates to the Optional Procedure for Filter Removal section for details.
- Spinel deformations: It is important to exercise cars when contemplating implantation in patients with significant kyphosobletic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may make percutaneous removal of the filter more
- In pallants with continued risk of chronic, recurrent pulmonary emboliam, patients should be returned to anti-thrombotic therapy as soon as it is deemed serie. If resistance is encountered during a lemonar insention procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium, if a large thrombus is demonstrated, remove the venipuncture needle and use the vein on the opposite side. A small thrombus to be proceed to the head of the contrast medium.
- thrombus may be bypassed by the guidawire and introducer.

 The introducer catheter has radiopaque markers to assist in visualization and predaployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location.
- between which the filter should be positioned just prior to unsheathing and deployment.

 11. The introducer catheter hub has a special Intamal dusign. Care should be taken to make con-
- nections firmly, but without excessive force that may seuse breakege of the hub.

 12. It is very important to maintain introducer catheirs prisency with the saline flush so that the ground against that holds and properly orients the filter legs does not become covered by did. This will interfore with filter deployment.
- 15 Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unshealthe the stationary litter by withdrawing the introducer catheter. Do not twist the pusher wire handle at anytime during this procedure

- Analomical variances may complicate insertion and deployment of the Recovery Cone® Removal System. Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of deficulties.
- Produce the measured of administration of exercise care when contemplating removing the GZ* Spinal deformations; It is important to exercise care when contemplating removing the GZ* Filter with the Recovery Cone* Removal System in patients with significant kyphosocilotic spinal deformations because the IVC may kollow the general course of such anatomic deformations. This may raquire advanced interventional techniques to remove the filter. Remove the GZ* Filter using the Recovery* Cone Removal System Only. (Reference Optional
- Procedure for Filler Removal for specific removel instructions).

 The cone must be fully retracted into the Y-adapter before connecting the system to the intro-
- ducer cotheter to ensure that the cone can be properly delivered through the catheter.

Note: Standards and guidelines developed by the Society of interventional Radiologista rec-ommend that patients with filters (either permanent or retrievable) be tracked and receive "rou-tine follow-up" subsequent to the placement of the daylice

See Reporting Standards for Inferior Vens Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters. Millward, S., et al.: J. Vaso Interv Radiol 2005; 16:441-443; Recommended Reporting Standards for Vens Cava Filter Placement and Patient Follow-up. The Participants in the Vens Caval Filter Consensus Conference: J Vaso Inter Radiol 2003; 14:5427-5432; Guidelines for the Use of Retrievable and Convertible Vens Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. Kaufman, J., et al.: J Vaso Interv Radiol 2006; 17:449-459.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the

Possible complications include, but are not limited to, the following:

- Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reporte of caudal migra-tion of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration may else be caused by improper deployment, deployment into clots and/or disbogement due to large clot burdens,
- Filter fractures are a known complication of yeing cave filters. There have been some reports of serious pulmonary and cardiac complications with vana cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
- Perforation or other acute or chronic damage of the IVC wall.
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the fifter, or originated from superior or collateral vessels.
- Deep vein thrombosis
- Caval thrombosis/occlusion
- Extravasation of contrast material at time of venacavogram.
- Hamatoms or nerve injury at the puncture site or subsequent retrieval site.
- Hemorrhage
- Restriction of blood flow
- Occlusion of small vassels. Distal embolization
- Infection
- intimal tear
- Stenosis at implant site.
- Failure of fitter expansion/incomplete expansion.
- Insertion site thrombosis
- Filter malposition
- Vassal injury Arterioverous fratula
- Back or abdominal pain Filter Tilt
- Hemothorax
- Organ Injury
- Phlagmasia carulas dolens
- Pneumothorax
- Posiphlebitic syndrome
- Stroke Thrombophlebilis
- Venous Ulceration
- Blood Loss Guidawira entrapment

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications, including death associated with the use of vens cave filters in marbidly obsespatients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Regulred

- H. Equipment required
 The following equipment is required for use:

 One G2* filter and Delivery System that contains:

 One 48cm, 7 Franch I.D. introducer catheter and dilator set

 One Storage tube with pre-loaded G2* filter and pusher delivery system

 0.038* 3mm J-tipped Guidewire, 110cm long or longer
- 18 gauge entry needle
- Saline
- Contrast medium

- Contrast modulm
 Sterile extonation tube for seline drip or syringe for seline infusion
 All basic materials for venigundure: Scalpel, #11 blade, local sneethesia, drapes, etc.
 If the physician chooses to parculanaously remove the GZ* Filter, the Recovery Cone* Removal System is available from C.R. Bard, Inc.

L. Directions for Use

Insertion of the 7 French Introducer Catholor and Preliminary Venography

- Select a sultable femoral venous access route, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.

 Prep. drape and anasthouse the skin puncture site in standard fashion.
- Select and open the filter package. Open Kit A Introducer Calheter package.
- Nick the skin with a #11 blade and portorm veniguncture with an 18-gauge entry needle.
 Insert the J-tipped guidowire and goodly advance it into the distal vena cave or that velo.

Precaution: if resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vain patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the vanipuncture needs and try the vein on the opposite aide. A small thrombus may be bypassed by the guidewire and introducer.

6. Remove the vanipuncture needs over the J-topod guidewire. Advance the 7 French introducer catheter (ogether with its tapered dilator over the guidewire and into the distal vans cava or the

Precaution: The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The indiopaque markers on the introducer catheter provide a "target" location between which the litter should be positioned just prior to uncheating and Remove the guidewire and dilator, leaving the introducer catheter with its tig in the distal vena

cava or illac vein. Flush Intermittently by hand or attach to the introducer catheter a constant saline drip infusion to maintain introducer catheter patency. soulion: The introducer catheter hub has a special internal design. Care should be taken

to make connections firmly, but without excessive force that may cause breakage in the hub. Perform a standard Infortor venacovogram (typically 30 mL of contrast medium at 15 mUs).

Check for caval thrombi, position of renat value and congenital anomalias, Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 Advance the introducer catheter to the selected level under fluorescopic control. The guidawire and dilater should be reinsected to facilitate this. For femoral insertion, the introducer catheter

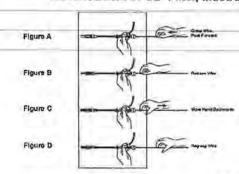
tip should be 1 cm below the lowest renal vein.

10. Remove the filter and delivery system from Kit B and flush with saline.

Presention: It is very important to maintain introducer cathelor patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over This will interfere with filter deployment.

- Attach the tree and of the filler storage tube directly to the introducer catheter already in the vein. The introducer catheter and filter delivery system should be held in a straight line to minimize motion.
- 12. Advance the filter by moving the nitinol pusher wire forward through the introducer catheter, advancing the filter with each forward motion of the pusher wire (Figures A-D). Do not pushed on the pusher wire, only advance the pusher wire forward. For the operator's convenience, the nitinal pusher wire may be looped, without causing kinking to the nitinal metarial, to facilitate pusher wire handling and advencement.

Advancement of G2º Filter, Illustrated



13 Continue torward industriant of the pusher wire until the fear tip advances to the radiopeque merker on the distall end of the introducer catheter. At this point, the pusher wire handle should be adjacent to the Y-adapter.

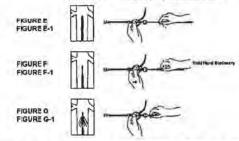
Filter Release/Deployment

14. Deliver and release filter se described below:

Figure S: Firmly hold the pusher wire handle. Keep this hand stellonery throughout the entire filter releases deployment process.

Figure E-1: Filter position ned in introducer catheter between the radiopagus markers prior to deployment in IVC.

G2º Filter Release, Illustrated



Precaution: Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unaheathe the stationary filter by withdrawing the introducer catheter as described below. Do not twist the pusher wire handle at enviling this pro-

Position the filter tip 1 cm below the lowest renal valu.

Figure F: With one hand held stationary, the other hand draws the Y-adapter and storage lub assambly back completely over the handle, uncovering and releasing the filler. Ensure that there is no elack or bend in the system during the filter rulesse/deployment process. The Y-adapter and storage tube assembly should be retracted in one emooth, continuous motion. Flaure F-1: Unsheathing of filter in IVC.

Figure G: The position of the hande at the completion of the unsheething process.

Figure G-1: The filter deployed in the IVC.

- Figure 6-1: The fluid abpoyed into tvo.
 15. Now withdraw the pusher wire back into the storage lube by firmly holding the Y-edapter, storage tube, and introducer catheter assembly and pulling back on the pusher-wire. —Do not twist the pusher wire handle at anytime during this procedure.
- 16. Resume the intermittent saline flush or constant drip infusion to maintain introducer catheter

Follow-up Vancavogram

- 17. A follow-up venacavogram may be performed after withdrawing the introducer catheter into the illiec vein (typically 30mL of contrast medium at 15mL/s).
- Remove the introducer catheler and apply routine compression over the puncture site in the usual way to achieve homostasis.

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

CAUTION: Remove the G2º Filter using the Recovery Cone® only.

Removal of G2* Filler

Equipment Regulred

The following equipment is required for use:

- One Recovery Cone® Removal System that contains: One 75 cm, 10 French I.D. Introducer catheter and dilator set
 One Y-adepter with Recovery Code* and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry naedle 12 French dilator
- Salina
- Contrast medium

(2)

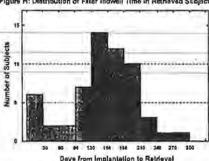
Case 2:15-md-02641-DGC Document 11012-2 Filed 05/07/18 Page 105 of 119

- Stante extension tube for asline drip or syringe for sellne infusion
- All basic majorials for vanipuncture; acalesi, #11 blade, local anesthesis, drapes, etc.

A clinical sludy involving 100 patients was conducted to assess the safety of removal of the GZ* Filler. 61 patients underwent a filter retrieval procedure in which 58 had successful retrieval of their filler. Of the 42 patients that did not have their filler retrieved, 6 died of unrelated causes, 3 withdraw. 2 became lost to follow up and 31 were alther not clinically indicated for filter retrieval or falled to meet retrieval eligibility criteria during the period in which the patient could be considered for filter retrieval eligibility criteria during the period in which the patient could be considered for filter retrieval per the protocol (within 6 months after filter plecament). The mean specifies of the 61 periods who underwork a retrieval procedure was 48 years with a range of 19,3-81.8. The indications for filter placement included DVT and/or PE with contraindication to anticoagulation, DVT and/or PE with complication or failure of anticoagulation, and prophylaxis.

The time to retrieve in the 58 patients with successful filter retrievals ranged from 5 to 300 days with a mean of 140 days and median of 144 days. Please see the histogram in Figure H depicting the time

Figure H: Dietribution of Filter Indwell Time in Retrieved Subjects



Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from Inability to engage the filter apex with the Recovery Cone® Removal System due to filter tilt teeding to embedding of the the filler apex with the reactivery corrections of the 58 successful filter retrievals involved a filter that was retrieved in apike of the 18 successful filter apex into cavel well.

There was one symptometic complication in the aludy. A patient reported low back path after a successful filter placement. On pre-relieval imaging, two (2) of the filter arms were found to be penetraling the cavel wall. The filter was successfully relieved and the pain resolved.

Asymptomatic complications included caude migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval atenosis at implant site post successful retrevel (n=1).

Procedural Instructions Insertion of the Introducer Catheter

- Select a suitable jugular venous access route on either the right or tell side depending upon the
- patient's size or anatomy, operator's preference, or location of venous thrombosts.

 Prep, drape and anesthetize the skin puncture site in standard fashion.
- Select and open the Recovery Cone® Removal System package. Open Kit A Introducer Cotheter package.
- Nick the skin with a #11 blade and perform venipuncture with an 18-gauga entry needle.
- Insert the guidewire and gently advance is to the location of the G2® Filter for removal.
- Remove the vanipuncture needs over the guidewire.
- Pre-dilate the eccessed vessel with a 12 French dilator
- Advance the 10 French introducer catheter together with its tapered dilator over the guidewite and into the vein NOTE: The introducer catheter has a radiopaque merker at the distal end of the catheter sheath

to sesist in visualization.

- Remove the guidewire and dilator, toeving the introducer catheter with life tip in the appropriate location. Flush intermittently by hand or attach to the catheters constant saline drip infusion to maintain introducer catheter patency.
- Perform a standard interior venecavogram (typically 30 mL of contrast modium at 15 mL/e). Check for thrombus within the filter, if there is significant thrombus within the filter, do not rethe GZ Filter.

Recovery Cones Removal System Insertion and Delivery

- Remove the Recovery Cone® Removal System and pusher system from Kit B.
- 12. Flush the central lumen of the cone catheter and wet the cone with saline-preferably hapainged saling
- Slowly withdraw the cone into the Y-adapter to collapse the cone and flush with saline PRECAUTION: The cone must be fully retracted into the Y-seapter before connecting the sys-tem to the introducer catheter to ensure that the cone can be properly delivered through the cetheter.
- 14. Attach the make end of the Y-adepter with the collapsed cone directly to the introducer catheter. The introducer catheter and filter delivery eyetem should be held in a straight line to minimize this.
- 15. Advance the cone by moving the pusher shall forward through the introducer catheter, advancing
- the cone with each forward motion of the pusher shaft.

 16. Conlinus forward movement of the pusher shaft until the cone advances to the radiopaque marker on the distal and of the introducer catheter. Unshaethe to open the cone by stabilizing the shall and retracting the introducer cathotes

Capture of G2º Filter

G2" Filter Removal, Illustrated

17. The capture of the G2® Filler is illustrated in Figures A-E;

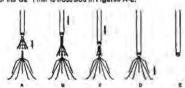


Figure A: After the cone has been opened superior to the filter, advance the cone over the filter tip by holding the introducer catheter stationary and advancing the pusher shalt. It is recommended to obtain an enterior-oblique fluoroscopic image to confirm that the cone is over the filter tip.

Figure B: Close the cone over the fiter tip by advancing the introducer catheter over the cone while holding the pusher shall stationary

Figure C: Continue advancing the introducer callieter over the cone until the cone is within the intro-

Figure D: With the cone collapsed over the filter, remove the filter by stabilizing the introducer catheter and retracting the pusher shall in one, smooth, continuous motion.

Figure E: The filler has been retracted into the cetholor.

16. Examine the filler to assure that the complete filler has been removed. Follow-up Venacavogram

- A follow-up venacevogram may be performed prior to withdrawing the introducer catherer (typi-cally 30 mL of contrast medium at 15 mL/s).
- Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guldewire - Assisted Technique

Oue to anatomical variances with respect to the position of the G2º Filter, guidewire-assisted lech-Use of a Guldewire

If it is difficult to align the cone with the G2* Filter tip, one may use a guidewire to facilitate advancement of cone over the filter Up.

Withdraw the introducer catheter and cone shall away from the filter tip, Insert a 0.035" guidewire through the central turnen (J-tipped or angled tip, a hydrophilo-coated guidewire is recommended). Advance the guidewire through the come and through the filter near the filter up.

After It has been confirmed that the guidewire is in contact with or in close proximity to the filter tip, edvance the cone over the guidewire to the filter (p.

Advance the Introducer catheter to slightly collepse the cone over the Filter tip. Withdrew the guidewire into the pusher shaft.

Continue removing the Filter as described in step 17.

J. How Supplied

Each GZ* Filter is supplied preloaded in a storage tube. Each GZ* Filter is sterile and nonpyropenic unless the package is demaged or opened, and is ready for single use only. The storage tube sidelivery system are pre-assembled. If the filter is inadventionly discharged, do not attempt to realadize or reload it

Warning: After use, the GZ^{Φ} Filter Delivery System and accessorise may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The Q26 Filter should be stored in a cool (room temperature), dry place. K. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from detects in melanisis and workmanship for a poriod of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the detect. product. In Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and lear from normal use or defects resulting from misuse of this product are not covered by this limited war-

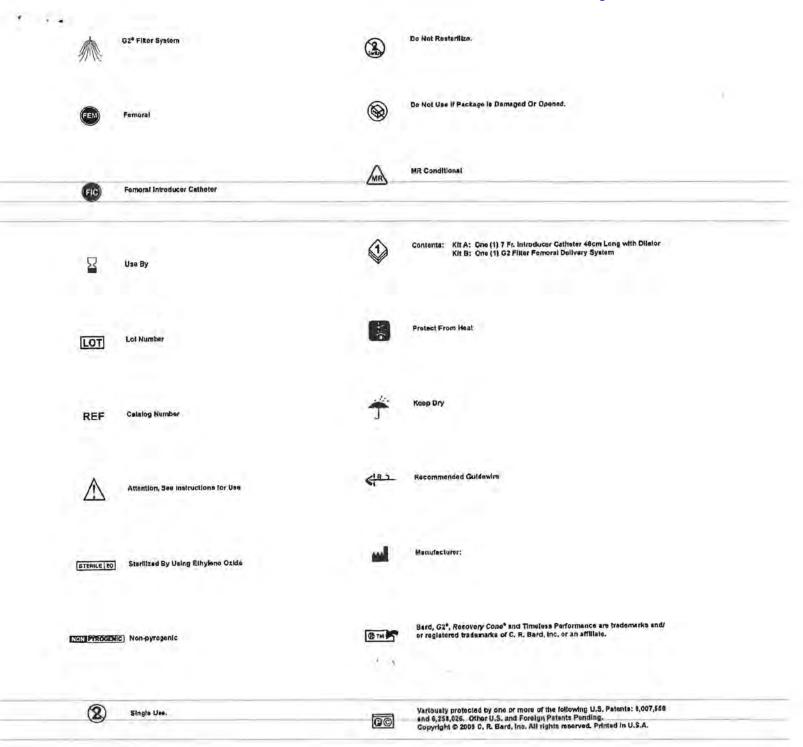
TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implicid warranties, incidental or consequential damages. You may be entitled to additional remedies under the lews of your state/country. An issue or revision date and a revision number for these instructions are included for the user's information on the leat page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is

For additional yana cave filter clinical information please refer to the following societal guldelines:

- "Practice Guideline for the Performance of Percentaneous Inferior Vana Cave Filter Placement for the Prevention of Pulmonary Emboliam" [ACR Practice Guideline 2007; 38:673-6841
- "American College of Chest Physicians: Opinions regarding the diagnosis and management of venous thromboembolic disease. ACCP Consensus Committee or Pulmonary Embolism. American College of Chest Physicians" [Chest 1998 Feb; 113[2]:
- "Practice Management Guidelines for the Prevention of Venous Thrombosmbolism in Traums Patients: The EAST Prectice Management Guidelines Work Group" [J Trauma 2002; 63:142-614]
- "Quality Improvement Guidelines for Perculaneous Inferior Vens Cave Filter Plecement for the Prevention of Pulmonary Embolism* [JVIR 2003; 14:5271-5275]

- Quality Improvement Guidelines for Percutaneous Permanent Inferior Vens Cava Filter Placement for the Prevention of Pulmonary Embolism. Grasel, Swan, Cardella, et al.: J Vasc Interv Rediol 2003: 14:S271-S275.
- Initial Exponence in Humans with a New Retrievable Interior Vena Cave Filter, Asch, M.: Radiology 2002, 225(3), 835-844.
- Rating The Recovery Vena Cava Fitter after Dwell Times Longer than 180 Days. Binkert, C., of all of Vasc Interv Radiol 2008, 17(2), 299-302. Experience with the Recovery Filter as a Retrievable Inferior Vena Cava Filter, Grande, J., et el.: J. Vasc Interv Radiol 2005, 18(9), 1189-1193.
- Difficult Retrieval of a Recovery IVC Filter, Hagspiol, K., et al.; J Vasc Interv Rediol 2004, 15(6), 645-647. Removal of Vene Cave Filter at 224 Days, Lipman, J.: Southern Medical Journal 2005, 98(5).
- 558.558 Retrievel of the Berd Recovery Filter from a Superior Vene Cava Rejan, D., et al.: J Vasc Interv Radiol 2004, 15(10), 1169-1171
- Retrievable inferior Vena Cava Filters: Initial Clinical Results. Resenthal, D., et al.: Annals of Vascular Surgery 2006, 20(1), 157-165.



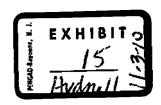


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PK5250500 Rev. 1 07/09

EXHIBIT EE



Document Detail

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POA-7081

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Product Opportunity Appraisal for Recovery Filter System

Document Version:

Release Date:

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Product Opportunity Appraisal for Recovery Filter System

Release Panel: Werner Tia Shifrin Kevin Carr Robert DeCant Len Dejohn Joe **Edwards Mary** Hudson Brian Krueger Bill

McDermott John

Files: poa-7081.doc



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PRODUCT OPPORTUNITY APPRAISAL

Date: 2/2/2005 4:44:52 FM 070018 Version : 000 Revision 000 Page J of 10

Ref: SOPN070002

Bard Division: BPV	
Project Name: Recovery	
Project Number: 7081	
Product Line: Filters	
Team Leader: Rob Carr	Marketing Representative: Janet Hudnali

Timing and Status:

	Start Date	End Date	Approval Date to Enter Next Phase
Phase 0- Concept / Feasibility			
Phase 1- Design & Development			
Phase 2- Design Qualification			
Phase 3- Process Qualification & Clinicals			
Phase 4- Market Release			

1. Executive Summary

Proj	ect Type and Duration (please mark only one box)		
	New Product Development	Distribution Agreement	
	Enabling Technology	CIP	
Estim	ated Project Duration, Phase 1 through Launch (phase 3)	months	

Summary Project Description. Include a brief overview of the product/ CIP/ transfer, the opportunity and business rationale.

The purpose of this project is to develop and commercialize a permanent IVC filter that is also removable after an extended period of implantation.

Venous thrombosis and pulmonary embolism constitute major health problems that result in significant morbidity and mortality. In the U.S. alone, it is estimated that venous thrombosis and pulmonary embolism contribute to 600,000 hospitalizations per year and that as many as 150,000 individuals die each year as a result of pulmonary embolism. Patients with various types of diseases, especially certain cancer patients, are at high risk for developing deep venous thrombosis (DVT) and pulmonary embolism (PE). Patients undergoing surgery (especially orthopedic, ob/gyn, urological, and neurosurgical) are also at high risk for venous thrombotic events. The standard treatment for people with thromboembolic disease is anticoagulation therapy. Current indications for percutaneous inferior vena cava (IVC) filter placement include patients with PE that cannot tolerate anticoagulation. In addition, IVC filters are increasingly being placed prophylactically in patients who are contraindicated for, or unresponsive to, anticoagulation. This includes patients at high risk of developing PE but who have not yet developed symptoms and patients with venous thrombosis, but without concomitant PE. It is widely believed that a temporary (or removable) filter might be a better option for prophylactic use and for patients with short-term contraindications to anticoagulation. Possible patient populations include young patients who require protection from PE but in whom doctors are disinclined to place a permanent cardiovascular implant.

ey Project Financials	
T\$2.4M 1st Yr Rev.s (incremental)	\$25.5M 3 rd Yr Rev.s (incremental)
Market Hat White dearwood analysis information that is the asset	Educated and provided an area of C. Q. Bord, Inc. Maither this document not the information therein may

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Ref:
SOPN070002

\$25.2M NPV

\$870,000 R&D Budget

2. Market / Customer / Device

Market Description. Include market definition, trends and opportunities as well as any segmentation information.

The current U.S. IVC Filter market totals \$114MM. The market leader as of October, 2002 is the TrapEase (Cordis Corp) with a 40% share. Long regarded as the "gold standard" for caval interruption, the Greenfield (Boston Scientific) has suffered from the introduction of TrapEase in July, 2000. The availability of a new filter, Gunther Tulip (Cook, Inc.), with its implied removability, has further negatively affected Greenfield's share. In addition to taking share away from Greenfield, the Gunther Tulip has also contributed to the growth of the entire filter market (which had been relatively flat for some time) by 17% between October, 2001 and September 2002. Bard's Simon Nitinol Filter has maintained its market share position at 11-12% despite the introduction of new products; however, we will need to introduce a new device with clear advantages in order to maintain and grow our IVC filter business moving forward.

The following points summarize the current IVC Filter market and project the future trends:

- Although the filter market is a mature one, it is still dynamic and susceptible to dramatic shifts when new devices and/or indications are introduced.
- Users can be swayed by ease of use, low profile, and aggressive marketing even in the absence of solid clinical history and in spite of documented negative clinical experiences.
- Optional/temporary filters will create a new category and expand the entire filter market.
- The majority of the growth in the vena cava filter market will come from the optional filter segment.
- Customers desire a filter that is durable enough to be a permanent filter, yet offer the flexibility of being able to be removed whenever the physician decides that mechanical caval interruption is no longer needed to protect the patient from a fatal PE.

Customer Requirements. Include performance, physical requirements, safety considerations, price tolerance, packaging requirements, special requirements for international markets and desired marketing claims (please reference sources)

Filter

- Must be designed so that it can be safely removed after an extended period of indwelling time.
- Exhibit clot-trapping efficiency comparable to currently available filters.
- Visible under fluoroscopy.
- Resist migration.
- MRI safe and compatible.
- Exhibit minimal tilting within the vena cava.
- Filter legs should not cross upon deployment.

Delivery System

- Flexible enough to navigate through tortuous anatomies associated with a left femoral introduction
- Allow safe and accurate delivery of the device into the intended location.
- Low profile (≤7F ID)
- Facilitate delivery of the filter in a centered manner.

Packaging

Adequately protect the device, yet be easy to store and handle.

Device Description If complete description (including materials, performance & features) is contained in an attached Design Document, feel free to reference. Description should match Project Profile

- Nitinol construction.
- Dual-level filter with 6 "arms" & 6 "legs"
- Designed for 28mm maximum caval diameter

Each filter shall be loaded into a 7F ID/9F OD delivery system designed for left or right femoral vein introduction.

Refer to Product Performance Specification (PPS) for complete description.

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Form

3. Competitive Analysis

Competitor & Product Name	Date on Market	Est. U.S. Market Share (\$)	ASP*	Strengths & Weaknesses from Performance/Feature Standpoint
Rounn Scientific (MediTech) Greenfield	1986	25%	\$985	S: Regarded as the "gold standard" of IVC filters. Extensive clinical history. W: Large profile, single level of filtration, tendency to tilt
Cook Gunther Tulip	Oct, 1900	12%	\$1,075	S: Extensive O.U.S. experience. First on the market with implied removability. W: Short implantation time (14 days), Single level of fibration. Tendency to tilt. Delivery & removal are not aver-friendly.
Cordis Trapliane	Jun, 2005	20%	\$1,002	S: Lowest profile device on the market, casy to use, only one system needed for both femoral and jugatar introduction. W: Many reported complications, questionable fifter design.
Cordis OptEase	Oct, 2002	13%	G ML	S: TrapEase market position. W: Short implemention time (12 days in Europe), Semoral zemoval may not be ideal for certain patient populations. Price.
B.Brasen Venatech	196 9	6%	\$950	S: "Doal Filter" - decreased inventory requirement W: Predicate device's history of guidewire entrapment; san be confusing, possibility of placing filter upside down.
Proposed Product** (est.)	Apr, 29 0 3	19%	\$1,300	S: First and only permanent filter that can be removed beyond two works after implication. Proven conical slape. Two-level filtration, Low profile. W: only available in femoral delivery, larger profile than Cordis filters

Average Selling Price

Competitive Analysis. Competitive assessment & assumptions including an analysis of competing/alternate technologies if appropriate.

There is currently no removable vena cava fifter available in the U.S. Clinical, Animal, and Bench data to date show that this product will most likely be indicated for removal well beyond the 12-14 day range that the competition is currently pursuing. This, in conjunction with the merits of its design as a caval filtration device, give Recovery a significant competitive edge.

Patents. Describe patent positions and strategy. If a complete description is contained in an attached Design Document, feel free to reference.

6,007,558 and 6,258,026

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^{**} Use estimated market share % for year 3

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4. Market Positioning & Timing

Product Positioning. Include price, performance & feature benefits to customer. Call point info & any training or reimbursement issues should be addressed as well.

<u>Positioning:</u> The first and only permanent filter that can be removed beyond 14 days after implantation.

List Price: \$1,395 ca.

Features (Benefits)

- Nitinol Construction
- Leg Spline
- Flex Hinge
 - Two-level filtration
- Arms down design
- Elastic Hooks

Call point: Interventional Radiologist, Vascular Surgeon, General Surgeon, Trauma Surgeon

Training: each physician should be thoroughly in-serviced by the sales representative prior to placing/removing the Recovery Filter

<u>Reimbursement</u>

Placement: 36010 - IVC catheter, 75825 - IVC gram, 37620 -Interaption, partial or complete, of IVC

Removal: 36010 - IVC catheter, 75825 - IVC gram, 37203 & 75961 - forcign body retrieval

There is currently no CPT code specifically for IVC filter removal.

Market Timing and Launch Strategy. Describe U.S. versus international launch plan. If LMR is planned, include rationale.

U.S.

Market introduction will occur in 2 phases:

Permanent indication

LMR is necessary for two reasons: 1) manufacturing capacity 2) targeting customers that will not attempt removals

Strategy: Take as much share as possible, Drive Recovery to be standard in caval interruption, and Grow the market

Removable indication

Launch objective will be to dispel the segmentation that has been created in the market place between "permanent" and "removable" indications.

International

LMR to begin with U.K. (objectives: gain additional clinical experience, glean positioning/targeting information, manage downside risk of potential adverac events prior to U.S. regulatory clearance for removable indication)

Market release will occur by each country once the BCs provide a marketing plan including an analysis of the opportunity and business rationale for commercialization.

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SOPN070002 Cannibalization. List current products that will be cannibalized or made obsolete by this product and quantify the impact Simon Nitinol Filter Year 1 - \$2M Year 2 - \$7M Year 3-\$9M 5. Clinical and Regulatory U.S. Please mark applicable ☐ IDE Clinical Feasibility ☐ No File Rationale PMA Supplement ☐ IDE x 510 (k) PMA Describe and comment on level and timing of activity European. Please mark applicable K CE Mark Self Certification Clinical Feasibility Type Testing Describe and comment on level and timing of activity Device already CE Marked at time of this report

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6. Financial Opportunity (Complete the following information in a spreadsheet/financial model)

U.S. Market		Yr.1	Yr.2		Yr.3		Yr.4		Yr.5
Market Size (\$)	\$	113,000,000	\$ 129,865,672	S	142,852,239	\$	157,137,463	\$	172,851,209
ASP		1,005	1,050		1,050		1,050		1,050
Market Size (units)		112,438	123,682		136,050	_	149,655		164,620
Growth			10%		10%		10%		10%
BPV:									
Market Share		3.00%	13.00%		19.00%		23.00%		25.00%
ASP		1275	1325		1300		1300		1275
Units '		3,373	16,079		25,849		34,421		41,155
Total Revenue (\$)	\$	4,300,746	\$ 21,304,154	\$	33,604,289	S	44,746,763	\$	52,472,688
Cannibalized Rev.	\$	2,000,000	\$ 7,000,000	\$	9,000,000	\$		5	
Incremental Rev.	\$	2,300,746	\$ 14,304,154	\$	24,604,289	\$	44,746,763	\$	52,472,688
Target cost (unit)		504.125	514.875		509.5		509.5		504.125
Target cost (total)	\$	1,700,481	\$ 8,278,473	s	13,170,296	\$	17,537,289	\$	20,747,289
Target Gross Margin (unit)	\$	770.88	\$ 810.13	\$	790.50	s	790.50	\$	770.88
Target Gross Margin (total)	\$	2,600,265	\$ 13,025,681	\$	20,433,992	\$	27,209,474	\$	31,725,399
Est. Gross Profit (Incr.units only)	5	1,391,049	\$ 8,745,776	S	14,961,300	\$	27,209,474	\$	31,725,399

^{*}If a specific launch date is assumed, Year 1 will only have sales for that calendar year.

Notes:

Assumes launch April, 2003 with permanent indication

Does not include the Recovery Cone

25% of revenue projected to come from Jugular/SubIclavian/Antecubital delivery options starting Yr. 2

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Int'l Market	2	003		2004		2005		2006	2007
Market Size (\$)	\$	20,000	S	21,000,000	\$	22,050,000	\$	23,152,500	\$ 24,310,125
ASP		1,000		1,000		1,000		1,000	1,000
Market Size (units)		20,000		21,000		22,050		23,153	24,310
Growth				9%		10%		9%	8%
BPV:									
Market Share		0.5%		2,3%		4.2%		6.5%	9.4%
ASP		1000		1000		1000	10.00	1000	1000
Units		105		491		930		1,515	2,276
Total Revenue (\$)	\$	105,000	\$	491,000	S	930,000	\$	1,515,000	\$ 2,276,000
Cannibalized Rev.	\$		\$		\$		\$	-	\$
Incremental Rev.	\$	105,000	\$	491,000	\$	930,000	\$	1,515,000	\$ 2,276,000
Target cost (unit)		445		445		445		445	445
Target cost (total)	\$	46,725	\$	218,495	\$	413,850	\$	674,175	\$ 1,012,820
Target Gross Margin (unit)	\$	555.00	\$	555.00	\$	555.00	\$	555.00	\$ 555.00
Target Gross Margin (total)	\$	58,275	\$	272,505	\$	516,150	\$	840,825	\$ 1,263,180
Est. Gross Profit (Incr.units only)	\$	58,275	\$	272,505	\$	516,150	\$	840,825	\$ 1,263,180

Notes:

Does not include Recovery Cone

25% of revenue projected to come from Jugular/Sublclavian/Antecubital delivery options starting Yr. 2

Note: Global Market is the summation of the above U.S. and International forecasts

Global Market	Yr.1	Yr.2	Yr.3	Yr.4	Yr.5
Market Size (\$)	\$ 113,020,000	\$ 150,865,672	\$ 164,902,239	\$ 180,289,963	\$ 197,161,334
ASP					
Market Size (units)	132,438	144,682	158,100	172,807	188,930
Growth					
BPV:					
Market Share (units)	3%	11%	17%	21%	23%
ASP	1267	1315	1290	1287	1261
Units	3,478	16,570	26,779	35,936	43,431
Total Revenue (\$)	\$ 4,405,746	\$ 21,795,154	\$ 34,534,289	\$ 46,261,763	\$ 54.748,688
Cannibalized Rev.	\$ 2,000,000	\$ 7,000,000	\$ 9,000,000	\$ -	\$
Incremental Rev.	\$ 2,405,746	\$ 14,795,154	\$ 25,534,289	\$ 46,261,763	\$ 54,748,688
Target cost (unit)	502	513	507	507	50
arget cost (total)	\$ 1,747,206	\$ 8,496,968	\$ 13,584,146	\$ 18,211,464	\$ 21,760,109
arget Gross Margin (unit)	\$ 764.36	\$ 802.56	\$ 782.32	\$ 780.57	\$ 759.56

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Target Gross Margin (total)	\$ 2,658,540	\$ 13,298,186	\$ 20,950,142	\$ 28,050,299	\$:	32,988,579
Est. Gross Profit (Incr.units only)	\$ 1,451,689	\$ 9,027,177	\$ 15,490,314	\$ 28,050,299	\$:	32,988,579

Notes:

Does not include Recovery Cone

25% of revenue projected to come from Jugular/SubIclavian/Antecubital delivery options starting Yr. 2

7. Project Cost

Note: For approval to move from Concept Investigation to Feasibility, <u>summary estimates of costs for the entire</u> <u>program and detailed estimates for the next phase</u> are required

For approval to move from Feasibility to Development, detailed estimates for the entire project are required. If these

costs are outlined in Operating Plan (PDOP, PROP) please reference.

	Expense	Notes:
R&D- Labor (hours and rates)	240,000	
R&D Materials	100,000	
Capital- Tooling & Equipment	800,000	
Clinical	500,000	50 patients, 4 sites
Packaging	30,000	Carton graphics, tooling for new tray design, packaging engineer labor
Regulatory	50,000	240 hours - two 510(k)s @ 80 hours; 80 additional hours for planning regulatory strategy and miscellaneous communication with FDA
Marketing - Product Launch (Promotions, Literature)	350,000	Hands-on workshops, brochure, animation,
Marketing - Other (i.e., IFU translations)	100,000	
TOTAL	\$2.17 M	

8. Business Rationale/ Strategic Fit

Address the business/strategic gains this project offers from both the product line and overall business standpoint. Please reference the Strategic Impact category and the Strategic Alignment score.

Strategic Alignment Score: 2

Strategic Impact Category: Innovation Leader

The Recovery Filter will give Bard an opportunity to take a leadership position in the Vena Cava Filter market. Clinical, Animal, and Bench data to date show that this product will most likely be indicated for removal well beyond the 12-14 day range that the competition is currently pursuing. This, in conjunction with the merits of its design as a caval filtration device, give Recovery a lignificant competitive edge.

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Offering a product that is so far ahead of the competition in terms of its ability to meet a previously unmet clinical need will position Bard as an innovator that is knowledgeable and concerned about the market, the disease state, and the needs of the customer. We will be able to leverage this image to gain business in other product lines as well as position us for future product

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9. Resources

Include project team member names and allocations to this project

Function	PHASE 1: Concept Investigation	PHASE 2: Feasibility	PHASE 3: Development & Clinicals
Marketing			Janet Hudnall
R&D			Rob Carr
Manufacturing			Frank Madia (GFO)
Quality			L. Buchanan Kopp & B. Hudson
Clinicals			Rob Righi
Regulatory			Mary Edwards
Materials / Ops			Rhondo Peck
Finance			Janei Fillinger

Attachments

Project Profile (including resource demand forecast)

2. Financial Model

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